RECORD #35

TITLE: Scope of Exemption in 10 CFR 20.303(d) for Disposal of Patient Excreta in Sanitary Sewars

FICHE: 66398-082

20, 303 (0)0379/8.



UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D. C. 20555

OCT 13 1982

MEMORANDUM FOR:

Herbert E. Book, Chief

Radiological Safety Branch

Region V, NRC

FROM:

William J. Olmstead

Director and Chief Counsel

Regulations Division

Office of the Executive Legal Director

SUBJECT:

SCOPE OF EXEMPTION IN 10 CFR 20.303(d)

FOR DISPOSALS OF PATIENT EXCRETA IN SANITARY SEWERS

This memorandum responds to your inquiry of August 31, 1982 to Karen Cyr, Attorney, Regional Operations and Enforcement Division, Office of the Executive Legal Director, requesting our views—on the scope of the exemption for disposals of patient excreta into sanitary sewers contained in 10 CFR 20.303(d). In particular, you ask whether the exemption includes disposals of patient excreta which do not follow a direct route from the individual to the sanitary sewer, such as, for example, disposals of urine which, after collection from the patient and prior to disposal in the sanitary sewer, are sent to a laboratory for analysis to determine the percentage of radioactive material excreted and retained. You also ask whether licensees are required to keep records of disposals covered by this exemption.

Although the question is not entirely free from doubt, it is our view, for the reasons given below, that as long as the two basic conditions of the exemption are satisfied, namely the matter to be disposed of must be excreta and the excreta must be obtained from individuals undergoing medical diagnosis or therapy with radioactive material, licensees are permitted to discharge patient excreta in sanitary sewers without limitation. It is also our view that exempt disposals of patient excreta should not be subject to the recordkeeping requirements of 20 CFR 20.401(b).

Section 20.303 specifies the conditions under which licensees may dispose of licensed material by release into a sanitary sewer system. Subject to one exception, section 20.303 provides that these releases must satisfy each of the following conditions:

In accordance with 10 CFR 20.6, these views do not consitute an interpretation which will be recognized as binding upon the Commission.

- The licensed material to be discharged must be readily soluble or dispersible in water.
- The quantity of any licensed or other radioactive material released into the sewer system in any one day may not exceed certain specified concentration and total quantity limits.
- 3. The quantity of any licensed or other radioactive material released into the sewer system in any one month, if diluted by the average monthly quantity of water released by the licensee, may not result in an average concentration which exceeds certain specified limits.
- 4. The gross quantity of licensed and other radioactive material released into the sewer system in any one year may not exceed certain specified curie limits.

Section 20.303 only exempts one type of discharge from all these conditions.

Section 20.303(d) provides in part that:

"Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section."

This exemption for patient excreta has been part of the Commission's regulations in 10 CFR Part 20 since the Commission first published its Standards for Protection Against Radiation in final form (22 FR 348, January 29, 1957, § 20.303). There has been no change in the text of the exemption since that time. The exemption did not appear in the proposed text of Part 20 as published for comment on July 16, 1955 (20 FR 5101) although the proposed rule, like the final rule, did contain a provision authorizing the disposal of licensed material into the public sewers (Proposed rule, § 20.33, Disposal into public sewers). Although the Commission received extensive comments on proposed Part 20 as published for comment in 1955, there were, so far as we can ascertain, no direct references to the basis or need for such an exemption.

The exemption first makes its appearance in a draft of Part 20 dated January 18, 1956. In this draft, the text of section 20.33, which contains the exemption reads as follows:

Section 20.33 <u>Disposal by Release into Sewers</u>

- (a) Except as provided in paragraph (4), licensed material released into a public sewage system shall meet the following conditions:
 - (1) The quantity of material released into a sewer in any one day shall not exceed the reger of i. or ii. following:

- the quantity which, if diluted by the average daily quantity of sewage released into the sewer by the licensee, will result in an average concentration equal to the respective value listed in Appendix B, Table I, Column 2; or
- ii. the quantity of byproduct material which may be possessed at one time under a general license, as provided by Section 30.21, Part 30; or the following respective quantity of source or special nuclear material

normal uranium, 1 lb. plutonium 239, 100 micrograms thorium, 1 lb. uranium 233, 10 milligrams uranium enriched in the isotope 235, 10 grams

- (2) The quantity of material released in any one month shall not exceed that which, if diluted by the average monthly quantity of water released by the licensee, will result in an average concentration equal to the respective value listed in Appendix B, Table I, Column 2.
- (3) Irrespective of the limitations of (1) and (2) above, the gross quantity of radioactive wastes released into a sewer shall not exceed one curie per year.
- (4) The licensee may propose alternative conditions to those in (1) through (3) in the license application if it is shown to the satisfaction of the Commission that the proposed conditions are not likely to result in the exposure of persons to doses of radiation or concentrations of radioactive materials in excess of those specified in Section 20.5.
- (b) Radioactive wastes excreted by humans are exempt from the limitations of this section.

This text was retained unchanged in a subsequent draft dated January 24, 1956. It is of interest that although these drafts included certain recordkeeping and reporting requirements (see sections 20.41 and 20.42), they did not contain a requirement that licensees keep records of disposals to public sewers.

The text of the exemption was retained unchanged in the February 1956 draft of Part 20. On February 28, 1956, it was suggested that the word "humans" be changed to "patients."

In a draft dated August 1956, the exemption, shown in comparative text, was again revised and given its present form.

§ 20.303 Disposal by Release into Sanitary Sewerage Systems

Human Excreta from individuals patients undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section.

Although section 20.303 was modified several times before Part 20 was published in final form on January 29, 1957, the text of the exemption for patient excreta remained unchanged. The August 1956 draft, like its predecessors, did not require licensees to keep records or make reports of disposals into sanitary sewers.

The requirement to keep records of disposals appeared in section 20.401(c) of the November 27, 1956 draft of Part 20 which provided that:

§ 20.401 Records of Surveys, Radiation Monitoring, and Disposal

(c) Each licensee shall maintain records in the same units used in the Appendices to this Part, showing the results of surveys required by Section 20.201(b), and disposals made under Sections 20.302, 20.303, and 20.304.

This provision was retained unchanged in the December 1956 draft and in section 20.401(c) of Part 20 as first published in final form on January 29, 1957. Although section 20.401 has since been amended, the requirement to keep records of disposals made under section 20.303 has remained unchanged.

Although the drafters of Part 20 apparently agreed that the exemption for patient excreta should be included in the regulations, it was evidently not considered a controversial matter and was not discussed in memoranda and other written documents prepared in connection with the original Part 20 rulemaking proceeding. Despite the fact that we have been unable to determine precisely what the drafters of Part 20 may have had in mind in including an exemption in Part 20 for disposals of patient excreta in

Compare drafts of Part 20, dated October 1, 1956, November 27, 1956 (Draft C), and December 1956 (Final draft attached to staff paper AEC-R/8.)

The October 1, 1956 draft did not contain recordkeeping requirements for disposals.

^{4/} Sections 20.302, 20.303 and 20.304 related respectively to Method for obtaining approval of proposed disposal procedures, Disposal by release into sanitary sewerage systems, and Disposal by burial in soil.

sanitary sewers, there is some evidence that the regulations relating to disposals in sanitary sewers were designed for the sole purpose of providing a convenient means of disposal for quantities too small to represent a considerable hazard under any conditions likely to be encountered.

The waste disposal portion (§§ 20.31 - 20.33) of the January 18, 1956 and January 24, 1956 drafts of Part 20, previously referred to, contained an introductory section which read as follows:

Section 20.31 General comments

It is impractical or impossible at the present time to devise, for burial in the ground or for release into sewers of large quantities of radioactive materials, uniform regulations which would provide adequate safety under the wide range of conditions which may be encountered. Disposal by burial or release into the sewage system may provide a convenient means of disposal for quantities too small to represent a considerable hazard under any conditions likely to be encountered. (Emphasis supplied).

Although this section was not retained in the text of Part 20 as first published in final form, it is indicative of the Commission's intent to limit disposals of radioactive material in sanitary sewers to minimal amounts. This objective was achieved in section 20.33 (now section 20.303) by establishing quantity and concentration limits for these disposals. Because of these limitations and because only relatively small quantities of waste were involved, it was understood that licensees would not be required to obtain specific permission from the Commission to make these disposals. The following quotation from testimony presented by Harold L. Price, Director, Division of Licensing and Regulation, U.S. Atomic Energy Commission, at Waste Disposal Hearings held February 3, 1959 by the Joint Committee on Atomic Energy supports this analysis.

"Because of the varied and complex technical problems which must be considered in the disposal of significant quantities of radioactive waste, the Commission's regulations do not attempt to spell out detailed 'Standards' in this area. Rather, they establish permissible concentrations in effluents to unrestricted areas and provide for the disposal of only minimal quantities of nuisance waste by release into sanitary sewerage systems and by burial in soil on a routine basis. These levels of activity are so low as to be considered permissible under any conceivable conditions of disposal. The regulation provides that the Commission will consider alternative methods and higher levels of waste disposal on an individual case basis." (Emphasis supplied).

In light of this background, it seems reasonable to conclude that the exemption for disposals of patient excreta in sanitary sewers was added, at least in part, because these disposals were considered to be sufficiently nonhazardous and limited in quantity that there was no need to insist that

sanitary sewers, there is some evidence that the regulations relating to disposals in sanitary sewers were designed for the sole purpose of providing a convenient means of disposal for quantities too small to represent a considerable hazard under any conditions likely to be encountered.

The waste disposal portion (§§ 20.31 - 20.33) of the January 18, 1956 and January 24, 1956 drafts of Part 20, previously referred to, contained an introductory section which read as follows:

Section 20.31 General comments

It is impractical or impossible at the present time to devise, for burial in the ground or for release into sewers of large quantities of radioactive materials, uniform regulations which would provide adequate safety under the wide range of conditions which may be encountered. Disposal by burial or release into the sewage system may provide a convenient means of disposal for quantities too small to represent a considerable hazard under any conditions likely to be encountered. (Emphasis supplied).

Although this section was not retained in the text of Part 20 as first published in final form, it is indicative of the Commission's intent to limit disposals of radioactive material in sanitary sewers to minimal amounts. This objective was achieved in section 20.33 (now section 20.303) by establishing quantity and concentration limits for these disposals. Because of these limitations and because only relatively small quantities of waste were involved, it was understood that licensees would not be required to obtain specific permission from the Commission to make these disposals. The following quotation from testimony presented by Harold L. Price, Director, Division of Licensing and Regulation, U.S. Atomic Energy Commission, at Waste Disposal Hearings held February 3, 1959 by the Joint Committee on Atomic Energy supports this analysis.

"Because of the varied and complex technical problems which must be considered in the disposal of significant quantities of radioactive waste, the Commission's regulations do not attempt to spell out detailed 'Standards' in this area. Rather, they establish permissible concentrations in effluents to unrestricted areas and provide for the disposal of only minimal quantities of nuisance waste by release into sanitary sewerage systems and by burial in soil on a routine basis. These levels of activity are so low as to be considered permissible under any conceivable conditions of disposal. The regulation provides that the Commission will consider alternative methods and higher levels of waste disposal on an individual case basis." (Emphasis supplied).

In light of this background, it seems reasonable to conclude that the exemption for disposals of patient excreta in sanitary sewers was added, at least in part, because these disposals were considered to be sufficiently nonhazardous and limited in quantity that there was no need to insist that

they meet the quantity and concentration limits applicable to other types of permitted disposals in sanitary sewer systems.

We have been unable to find any documents which explain why recordkeeping requirements for disposals (§ 20.401(c) as promulgated January 29, 1957; now § 20.401(b)) were added to Part 20. It is reasonable to assume, however, that this provision was included to enable the Commission to determine whether licensees were in fact making disposals, including disposals into sanitary sewers, in accordance with regulatory requirements. Since disposals of patient excreta in sanitary sewers are exempt from all regulatory requirements, there would appear to be no need to require licensees to keep records of these disposals.

Upon first impression, the text of the exemption for patient excreta, as set out in section 20.303(d) appears fairly straightforward. The exemption applies to a particular class of material—excreta, obtained from a specific source—individuals undergoing medical diagnosis or therapy with radioactive material. The exemption permits licensees to discharge into the sanitary sewer system for purposes of disposal and without limitation any matter which meets both these conditions.

Upon closer examination, the exemption becomes ambiguous, primarily because it is silent on several points. For example, the exemption does not specify when disposals of exempted excreta must be made. Nor does the exemption specify the manner in which these disposals must be made. The exemption contains no requirement that the disposal be made by the patient directly into the sanitary sewer. Absent such a requirement, the exemption would appear to be applicable to excreta collected in a bedpan, urinal or other container and subsequently emptied into the sanitary sewer. The text of the exemption also provides no basis for excluding from the exemption a scenario in which a portion of a patient's excreta is collected in a specimen container, held for a period of time for medical tests, and subsequently disposed of by pouring the excreta from the container into the sanitary sewer. As long as the two basic conditions of the exemption are satisfied, namely the matter to be disposed of must be excreta and the excreta must be obtained from individuals undergoing medical diagnosis or therapy with radioactive material, licensees are permitted to discharge patient excreta in sanitary sewers without limitation.

A more troublesome portion of the text of the exemption can be found in the statement that "Excreta . . . shall be exempt from any limitations contained in this section." (Emphasis supplied). The underlined text has been cited as authority for the view that the exemption does not relieve licensees of the requirement in 10 CFR 20.401(b), a different section, to keep records of disposals made to sanitary sewers in accordance with the provisions of section 20.303, including disposals of patient excreta exempted from the limitations of that section. To adopt this interpretation, however, not only presents certain practical difficulties; it also produces some rather absurd results.

The problem becomes readily apparent when one inquires what kind of information licensee records of patient excreta disposals should contain. Under the exemption, patient excreta may be discharged into sanitary sewers without regard to quantity or concentration limits. No prior measurements are needed before making the disposal. To require licensees to perform measurements of these disposals for recordkeeping purposes would, in our view, seriously erode the exemption. On the other hand, to require licensees to keep records of disposals which contain no measurements and only show the total number of disposals that have been made, would make a mockery of the recordkeeping requirement.

Despite the specific language of the exemption, it is our opinion, based on the preceding analysis, that the better legal view would be to limit the reach of the recordkeeping requirement in section 20.401(b) to disposals subject to the limitations in section 20.303 and to exclude exempt disposals of patient excreta from this recorkeeping requirement. One caveat should be noted. The preceding analysis does not address whether there is adequate justification, from the standpoint of radiological health and safety, for exempting disposals of patient excreta from the regulatory requirements applicable to other disposals in sanitary sewers. This question should be considered and resolved in connection with the overall revision of 10 CFR Part 20 on which the staff is currently working.

William J. Olmstead
Director and Chief Counsel
Regulations Division
Office of the Executive
Legal Director

DISTRIBUTION

JMapes
WJOlmstead
OELD R/F
OELD S/F
Regs R/F
Central Files
Joanna Becker

James Lieberman Karen Cyr Vandy Miller Walt Cool, HEBR Robert Baker, RES Leo Higginbotham, IE

C :::_D	:OELD	•		•	• •	•
· · · · · · · · · · · · · · · · · · ·	:Wolmstead	•	4			
TE::1713/82	:10//3 /82	•				



UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D. C. 20555

OCT 01 1982

MEMORANDUM FOR: Thomas F. Dorian, Attorney

Regulations Division, ELD

FROM:

Vandy L. Miller, Chief

Material Licensing Branch

Division of Fuel Cycle and Material Safety, NMSS

SUBJECT:

REQUEST FOR INTERPRETATION - 20.303(d)

This is in reference to the August 31, 1982 memorandum from H. E. Book, Region V, to Karen Cyr, ELD, requesting an interpretation of 10 CFR 20.303(d) and your September 17, 1982 note requesting our reaction to the memorandum.

With regard to the problem stated in Mr. Book's memorandum, we believe that patient excreta is exempt from the characteristic, quantity and concentration restrictions in 10 CFR 20.303(a)-(d), inclusive. We believe that this is true regardless of whether (a) the excreta is discharged by the patient directly into the sewerage system or (b) it is held for analysis, manipulation, and/or decay in storage and then released by the licensee's staff to the sewerage system. We do not believe that 10 CFR 20.401(b) and 10 CFR 30.51 relieve licensees of the responsibility for maintaining records of the disposal of patient excreta. However, as a part of the revision of 10 CFR Part 20, consideration should be given to exempting medical licensees from maintaining records of disposal of patient excreta.

Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety, NMSS

cc: Robert Baker, RES



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION V

1450 MARIA LANE, SUITE 210 WALNUT CREEK, CALIFORNIA 94596

August 31, 1982

MEMORANDUM FOR: Karen D. Cyr

Office of the Executive Legal Director

FROM:

H. E. Book, Chief

Radiological Safety Branch

Region V

SUBJECT:

REQUEST FOR INTERPRETATION - 20.303(d)

Description of Situation

During an inspection in July, 1982, a Region V inspector asked a technologist in a nuclear medicine laboratory the rather general question whether any I-131 waste was disposed to the sanitary sewer. When the answer was affirmative, the inspector asked to see the record of such disposals required by 20.401(b). He was told that no records were kept. On the basis of that information, a Notice of Violation was issued, including a citation for noncompliance with 30.51(a) and 20.401(b), both of which require records of disposals.

When the licensee responded, he stated that urine collected during uptake studies and containing I-131 was disposed to the sanitary sewer after being held for some decay. While some records were maintained, they did not include the quantity of I-131 in the urine at the time of disposal. The physician stated as part of his corrective action, the quantity of I-131 in microcuries was now being recorded for each such disposal.

Statement of the Problem

NRC Regulation 10 CFR 20.303(d) in the last sentence states, "Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section." The question arises - are there any limitations or qualifications to this exemption?

For some time, I have been aware of some rather strong disagreements on this matter. On one hand, there are those (including me) who believe the exemption is exactly that, and in spite of collection, analysis, manipulation, and storage in the laboratory, the material is still exempted urine and may be disposed to the sanitary sewer without records or other regulatory controls.

On the other hand, there are those who maintain that the exemption applies only to excreta in the direct route from the individual to the sanitary sewer, but does not apply under some other sixuations. For instance, the urine may

be collected and sent to a laboratory to determine the percentage of I-131 excreted (and retained). This permits the physician to more accurately prescribe subsequent doses of the radioactive material. This was the case in the present situation. The argument is, that in such cases, as a result of the collection, analysis, manipulation, and storage process, the material takes on the status of a "laboratory sample," and it should thereafter be treated as normal radioactive waste. It should be noted that in these cases the urine does not lose its identity as urine. It does not change form, and no radioactivety is added to or removed from it.

In the present situation, we are telling the licensee that we are requesting an interpretation of the regulations. We suggest that he continue to maintain records of the disposals, but that we will inform him of the contents of the interpretation when received.

Your assistance in this matter is appreciated.

A. E. Book

Herbert E. Book, Chief Radiological Safety Banch

cc: J. Joyner, RI
A. Gibson, RII
J. Miller, RIII
G. Brown, RIV
Vandy Miller, NMSS
Leo Higginbotham, IE

Ed Flack, IE