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10 CFR Part 20

Biomedical Waste Disposal

AGENCY:

Nuclear Regulatory Commission.

ACTION:

Final rule.

SUMMARY:

The NRC is amending its regulations to permit licensees greater leeway in disposing of liquid scintillation media and animal carcasses containing tracer levels of hydrogen-3 (tritium) or carbon-14. These rule changes will primarily affect NRC licensed hospitals and medical research institutions. Most licensees presently dispose of these items by sending them to a radioactive waste burial ground or by obtaining special authorization from NRC for incineration or onsite burial. Under the new regulations. the licensee may dispose of specified concentrations of these materials without regard to their radioactivity. The NRC is also amending its regulations to raise the annual limits for disposal of hydrogen-3 and carbon-14 by release to the sanitary sewerage systems. The rule changes will conserve waste burial capacity that is already in short supply.

EFFECTIVE DATE:

March 11, 1981.

ADDRESSES:

Copies of the value/impact analysis and the analysis of comments received may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C. Single copies of the value/impact analysis are available from John R. Cook, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301-4274240).

FOR FURTHER INFORMATION CONTACT:

John R. Cook. Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301-427-42401.

SUPPLEMENTARY INFORMATION:

Background

Radionuclide tracers are used extensively in biomedical research and for the diagnosis of diseases in humans. One of the end products of these research and medical activities is radioactive wastes. These wastes are usually shipped to radioactive waste burial grounds although certain water soluble or dispersible wastes are released into sanitary sewerage systems. Two of the most commonly used radionuclides in biomedical research (and to a lesser extent in medical procedures) are hydrogen-3 and carbon-14. The concentrations of these radionuclides in biomedical waste are minute, generally less than 0.05 microcuries per gram.

Liquid scintillation media and animal carcasses, both containing tracer quantities of hydrogen-3 or carbon-14, constitute the largest volume of radioactive biomedical waste.

Liquid scintillation counting has become a widespread technique for detecting radioactivity in biological samples such as blood or urine. Typically, a fraction of a milliliter of the biological sample containing tracer levels of hydrogen-3 or carbon-14 is combined with 20 milliliters or less of an organic solvent, primarily toluene, in a small vial to make a liquid scintillation medium. The vial is placed in a liquid scintillation counter, and the biological sample is assayed. The vials are used once and then collected for shipment to a radioactive waste burial ground.

Research laboratories and hospitals throughout the country presently use between 84 and 159 million vials per year. which represents between 200,000 and 400,000 gallons of liquid scintillation media. Disposal of this waste in radioactive waste burial grounds requires approximately 400,000 cubic feet of space at a cost of over $13 million per year for packing materials, transport, and disposal (this does not include the cost of licensee labor or overhead). Liquid scintillation media are approximately 43% of the total volume of radioactive waste shipped to burial grounds that is not related to industrial applications or nuclear power generation and its supporting fuel cycle.

Animals are used in research mainly for the development and testing of new drugs. Virtually every chemical compound that is considered for use as a human or veterinary drug is first tagged with a hydrogen-3 or carbon-14 tracer and injected into research animals to study how the chemical compound behaves. These research animals include mice, rats, dogs, monkeys, swine, and sheep. The animal carcasses containing tracer quantities of hydrogen-3 and carbon-14 are usually shipped to radioactive waste burial grounds. Animal carcasses annually require about 80 thousand cubic feet of burial space at a cost of almost $3 million per year. Animal carcasses are approximately 9% of the total volume of radioactive waste shipped to burial grounds that is not related to

industrial applications or nuclear power generation and its supporting fuel cycle.

There are other hydrogen-3 and carbon-14 waste streams in the research laboratory that do.not result in liquid scintillation vials and animal carcasses: for example, the solutions and attendant material used to prepare the research samples. These materials also contain tracer levels of hydrogen-3 and carbon-14.

Under present NRC regulations. hydrogen-3 and carbon-14 wastes that are readily soluble or dispersible in water can be disposed of by release to the sanitary sewerage systems. The annual limit for release to the sanitary sewerage systems is found in 10 CFR 20.303 and is limited to a total of 1 curie for all radionuclides per year for each licensee. Several associations of academic institutions have together asked the Radiation Policy Council to suggest that NRC raise this limit to 5 curies per year for hydrogen-3. 1 curie per year for carbon-14, and 1 curie per year for all other radionuclides. This rule amends the regulations accordingly This change will result in a negligible addition to the level of these radionuclides already present m the natural environment.

There are alternatives for disposal of liquid scintillation media and animal carcasses containing hydrogen-3 and
carbon-14 other than consignment to a radioactive waste burial ground. Liquid scintillation media can be evaporated, distilled, burned, or buried on a licensee's site if an appropriate location is available. Animal carcasses can be incinerated in a pathogen incinerator. Currently, one of these alternatives

to radioactive waste burial are readily available. Generally, liquid scintillation media and animal carcasses with any added hydrogen-3 or carbon-14 are being handled as radioactive waste and consigned to a radioactive waste burial ground under NRC's regulations (10 CFR 30.41 and 20.301) and similar Agreement State regulations.

The state agencies that control the existing radioactive waste burial grounds do not want to accept liquid scintillation media or animal carcasses. Liquid scintillation media are flammable and are suspected of leaching other radioactive chemicals out of the burial trenches. Also, some of the shipping containers arrive at the burial grounds leaking. Liquid scintillation media are chemically toxic and are suspected of being carcinogenic and thus pose a waste hazard unrelated to their radioactive character. Animal carcasses decompose and can be a pathogen hazard. Sometimes the animal carcasses will cause their containers to burst during shipment. The voids formed in the burial trenches by the decaying animal carcasses are also believed to contribute to migration of chemicals by increasing ram water percolation in

the trenches.

The three operating commercial radioactive waste burial grounds in the U.S. are located in Barnwell, South Carolina; Beatty, Nevada; and Richland, Washington. The Richland, Washington and Beatty, Nevada sites accept both liquid scintillation media and animal carcasses. However, after December 1984, the Richland, Washington site will not accept liquid scintillation media. The Barnwell, South Carolina site does not accept liquid scintillation media but does accept animal carcasses. At all three sites. the state regulatory bodies are attempting to reduce the volume of incoming waste to prolong site use.

During a temporary state-imposed embargo in mid-1979, some hospitals and research institutions across the country apparently came within days of curtailing operations involving liquid scintillation counting and animal research before the radioactive waste burial grounds in Richland, Washington and Beatty, Nevada resumed accepting liquid scintillation vials and animal carcasses.

The Rule

This Final rulemaking will allow NRC licensees to dispose of liquid scintillation media and animal carcasses containing less than 0.05 microcuries of hydrogen-3 or carbon-14 per gram without regard to their radioactivity. This regulation will not relieve licensees from complying with other applicable regulations of federal, state, and local government agencies regarding the disposal of non-radioactive materials. Scintillation media are toxic and flammable, and animal carcasses are sometimes pathogenic. These characteristics, which are a more important public health problem than their radioactivity, may require them to be disposed of under applicable federal, state, and local laws governing chemical and biological hazards. This rulemaking will also allow licensees to dispose by release to sanitary sewerage systems of up to 5 curies of hydrogen-3 and 1 curie of carbon-14 per year, in addition to the presently allowed 1 curie per year for all radionuclides. Neither the rulemaking allowing disposal of liquid scintillation media and animal carcasses without regard to their radioactivity nor that raising the limit for disposal of hydrogen-3 and carbon-14 to sanitary sewerage systems, authorizes disposal of liquid scintillation media (e.g., toluene) into the sanitary sewerage systems.

The rule will essentially remove any NRC restrictions on the disposal of liquid scintillation media and animal carcasses. It will no longer be necessary for NRC licensees to ship these materials, which could pose a chemical and biological hazard, up to thousands of miles across the country for disposal in a radioactive waste burial ground. NRC Agreement States could make similar amendments to their regulations in order to extend the benefit of

this action to their licensees.

The value/impact analysis prepared by the NRC staff to support the rule concludes that this rule change is the best solution to the problem of disposal of liquid scintillation media and animal carcasses containing tracer amounts of hydrogen-3 and carbon-14. If also adopted by the Agreement States. this action would save hospitals and research institutions in excess of $13 million annually ($16 million for the cost of packaging materials, transportation, and disposal, minus the $3 million estimated for non-radioactive waste disposal). Also, it will save almost one-half million cubic feet of radioactive waste burial capacity annually, or half of that used for radioactive waste not related to industrial applications or nuclear power generation and its supporting fuel cycle.

The value/impact analysis indicates that the action is non-substantive and insignificant from the standpoint of environmental impact. The amount of hydrogen-3 and carbon-14 that might be released to the environment each year as a result of the rule change pertaining to scintillation media and animal carcasses is small (28 curies and 6 curies respectively), particularly when compared to the steady state environmental inventory of 28 million curies of hydrogen-3 and 280 million curies of carbon-14. Calculations employing conservative assumptions indicate that if radiation exposure occurs as a result of the rule change, the maximum dose to exposed individuals is likely to be less than 1 millirem per year.

The value/impact analysis shows that highest estimated collective dose results from the assumed incineration of all 6 curies of carbon-14 contained in liquid scintillation media and animal carcasses. We calculate this release will result in a total of about 0.4 health effect during the next 1,000 generations. The average lifetime dose per person would be about 0.000001 millirems (this is a fraction of a percent of the dose and health effects attributable to natural background radiation). U incineration were to continue for the next 50 years, the average lifetime dose would be about o.00005 millirem (for perspective, the average dose per person from a coast-to-coast airline night is about 2.5 millirem). Further, the doses resulting from incineration of hydrogen-3 or the release to the sanitary sewerage systems of hydrogen-3 and carbon-14 are calculated to be much less than the dose from incineration of carbon-14.

In summary, the amendments concerning the disposal of tracer levels of hydrogen-3 and carbon-14 in liquid scintillation media and animal carcasses are appropriate because (a) the amendments will not pose an unreasonable risk to the common defense and security and to the health and safety of the public:

(b) disposal of these wastes in radioactive waste burial grounds is expensive

and without benefit commensurate with the expense: (c) the flammability of liquid scintillation media (organic solvents) and the decomposition of animal carcasses cause a significant problem in transporting these wastes to burial grounds: and (d) these wastes consume a significant portion of radioactive waste burial capacity which is in short supply.

Similarly, the amendment raising the limit for sanitary sewerage disposal of hydrogen-3 and carbon-14 is appropriate because it will not pose an unreasonable risk to the public. In addition, the shipment of this waste to radioactive waste burial grounds is costly and consumes valuable burial space that could be made available for more hazardous radioactive waste.

The Comments

This rule was published as a proposed rule in the Federal Register of October d. 1980 (45 FR 67018). The final rule is essentially the same as the proposed rule except for minor editorial changes and an additional statement regarding the non-radioactive hazardous and toxic properties of the wastes. This additional statement was included at the request of the Environmental Protection Agency and is discussed below under the heading Fate of Wastes. The Federal Register notice on the proposed rule contained essentially the same background information provided above, and invited public comments for a 45 day period ending November 24. 1980.

NRC received 321 comments on the proposed rule from academic institutions, medical facilities, state governments, professional groups, private individuals and special interest groups. Two hundred seventy one commenters supported the rule, 44 opposed it and 7 commented without indicating support or opposition. The comments supporting the rule came primarily from institutions, professional groups and individuals whose work would benefit from the rule and they cited those benefits both to their research and to society. The comments opposing the rule were split between individuals who were opposed to any release of radioactive material into the environment and individuals or special interest groups who were concerned about where this rule would lead, e.g., to a policy of dispersal of radioactive material as opposed to containment.

The comments addressed the following aspects of the proposed rule.

Need

Most of the 271 commenters who supported the rule stated their reasons. Their reasons are basically the same as those stated in the preamble to this rulemaking. The estimates of annual savings offered by the commenters if the proposed regulations went into effect ranged from $2,000 - $250,000, depending

on the size of the institution's biomedical program. Some of the organizations that supported the rule were the National Institutes of Health, the American Medical Association, the American College of Nuclear Physicians, the American College of Radiology, the American Hospital Association, the joint Commission on Accreditation of Hospitals, the Society of Nuclear Medicine, the Endocrine Society, the American Council on Education. Scientists for Public Safety and the Intersociety Council for Biology and Medicine.

A few of the opposing comments questioned the need for the rulemaking. One of these commenters asked. "If there were no space problems, would the question of changing the regulations ever have arisen?"

The answer to this question is, yes, the regulations need changing even without the problem of space in the burial grounds because present regulations impose an economic and administrative burden on licensees that is not justified. As one commenter who favored the proposed rule observed:

" . . . My own experience is that the strict regulations now in effect have resulted in the holding of hundreds of dead carcasses until money becomes available for proper packaging of these materials for disposal. The result has been a significant reduction in research and a reluctance to undertake projects which involve low levels of radioactivity in animals. Thus, my experience indicates that present restrictions have inhibited research . . ."

There are additional reasons for the rule changes regarding safety at the burial grounds, transportation to the burial grounds and safety in the laboratory. The problems in shipping these wastes to the burial grounds and the problems that these wastes cause in the burial trenches are discussed above under Background. Regarding safety in the laboratory, one commenter favoring the regulation observed:

"I believe the effort expended in meeting previous regulations has been more damaging to the health of my laboratory personnel than the small amount of radiation,i.e., difficulties of lung and skin exposure to toluene-based fluids (despite the use of hoods, gloves, etc.). I hope these hazards will decrease with these rules."

Scope

While one-third of the commenters supporting the rule urged NRC to expand the scope of the rule to include other hydrogen-3 and carbon-14 waste streams or to include other radionuclides in various waste streams. several of the commenters opposing the rule urged NRC to abandon the rule because it might lead to other rulemakings identifying further waste streams or radionuclides as candidates for disposal without regard to their radioactivity. These latter

comments most often cited the need for a comprehensive environmental analysis covering all possible radionuclides and all possible waste streams as their reason for opposing this present rulemaking.

The Commission is aware of the merit of having one comprehensive rulemaking to include many or perhaps all of the possible radionuclides and waste streams. This type of comprehensive rulemaking and its associated generic environmental analysis of all of the benefits and risks is theoretically an optimum approach, but as a practical matter it is an unworkable approach. The practical approach is to examine the specific waste streams which contribute a large volume to the burial grounds as candidates for alternative regulatory approaches. The U.S. Radiation Policy Council at their September 25, 1980 public meeting discussed both the generic approach and the specific waste streams approach. At that meeting the Council:

"Adopted a Federal policy acknowledging that there are concentrations of specific radionuclides in specific waste streams which pose such small risks that control for radiation protection purposes is not necessary. In accordance with this policy requested that the NRC present to the (Council's) Working Group by November 18 an interim plan for identification and analysis of specific waste streams beginning with the C-14 and H-3 (tritium) medical waste streams for which early action is appropriate and develop a proposed regulatory framework for this activity.

Single copies of that interim plan, called for by the Council, are available from John R. Cook at the above address.

Fate of Wastes

Several commenters, both for and against the proposed rule, expressed concern about the fate of these biomedical wastes if the NRC allowed disposal without regard to their radioactivity. Most of these commenters were concerned that the liquid scintillation medium toluene, which is flammable and toxic, would be poured down the drain and into the sanitary sewerage systems. The Environmental Protection Agency (EPA), while supporting NRC's amendment covering liquid scintillation media and animal carcasses, recommended that the regulation itself include a clarifying statement that disposal of scintillation media and animal carcasses without regard to their radioactivity will not relieve licensees from complying with other applicable regulations of federal, state and local government agencies regarding chemical and biological hazards. This recommendation was echoed by two other commenters. Also, a group of sanitation workers expressed concern that they might face an increased occupational hazard from the radioactive wastes, which they believed might concentrate in certain sewerage system components.

The preambles to both the proposed rule and this final rule include a statement similar to that recommended by EPA and others. However. the Commission agrees with EPA and those commenters who would like to see such a clarifying statement in the regulation itself regarding the non-radioactive hazards of liquid scintillation media and animal carcasses. Therefore, a statement has been added to the final rule at 10 CFR 20.306(d) as follows:

"(d) Nothing in this section relieves the license from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials."

Finally, regarding the question of a radiation hazard to sanitation workers from deposition in sewerage system components, because the hydrogen-3 and carbon-14 behave chemically the same as non-radioactive hydrogen and carbon. there is no reason to expect significant deposition or accumulation in sewerage system components. Further, hydrogen-3 and carbon-14 emit weak beta radiations, which are completely shielded by piping, conduit, ground, water, etc.

Concentration Limit

A few commenters questioned the concentration limit in the proposed rule which

was set at 0.05 microcuries or less of hydrogen-3 or carbon-14. per gram of liquid scintillation medium or animal tissue. Some commenters simply asked about the basis for the 0.05 microcuries per gram value. One commenter said the concentration limit should be raised to 0.1-0.2 microcuries per gram. Another commenter said that the concentration limit should be lowered to 0.02 or 0.025 microcuries per gram.

The commenter who suggested raising the concentration limit said that this could be done on the basis of the analysis of risks due to releases at these levels. The commenter who suggested lowering the proposed concentration limit offered an analysis which shows that 0.05 microcuries per gram is too high an activity for liquid scintillation counting and that 0.02 microcuries per gram will cover most applications of liquid scintillation counting. This latter commenter pointed out that the "as low as is reasonably achievable" (ALARA) concept of radiation protection dictates going to the lower concentration limit. This same commenter argued for an overall release limit for each licensee based on his analysis which assumes that all of the 200.000 - 400.000 gallons of liquid scintillation media are released at the maximum 0.05 microcuries per gram level.

The 0.05 microcuries per gram concentration limit was recommended to the Commission by its expert consultants as a level that would cover most

biomedical research involving tracer use in animals. The Commission adopted the same level for liquid scintillation media as an administrative simplification, recognizing that the 0.05 microcuries per gram level will be higher than that normally encountered in liquid scintillation work. If the limit were set much closer to the concentrations actually used, licensees would be required to perform more exacting calculations and analytical steps to demonstrate compliance with the rule. This adds to the cost of administration for both the licensees and NRC. Setting the concentration limit at 0.05 microcuries per gram for both animal carcasses and liquid scintillation media does not violate the ALARA principle because the concentrations actually used are controlled by the sensitivity of the counting equipment and the cost of hydrogen-3 and carbon-14 labeled compounds which typically are quite expensive.

The Commission derived its estimates of the potential quantities of hydrogen-3 and carbon-14 released to the environment as a result of this rulemaking from actual production and use data. It would be erroneous to assume that all of the liquid scintillation media would be released at the maximum 0.05 microcuries per gram concentration. This assumption leads to release estimates that exceed the total produced for such uses.

Basically, the value/impact analysis does not indicate the need for a maximum release limit for each licensee. The Commission does not believe that setting the concentration limit higher than that actually used in practice will result in unnecessary (non-ALARA) releases to the environment. The Commission does believe that these higher limits will reduce the cost of administration of these regulations.

Value/Impact Analysis

Several commenters both for and against the proposed rule commented on the preliminary value/impact analysis. A few commenters suggested that the final value/impact analysis consider the impact of multiple users on a common sewerage system disposing of hydrogen-3 and carbon-14 under the new limits. Also, the Environmental Protection Agency recommended lower dilution {actors for this part of the analysis. The Commission agrees with these comments and the final value/impact analysis addresses the impact of multiple users and employs adjusted dilution factors. The conclusion of the analysis, however, has not changed, i.e., the amendment raising the limit for sanitary sewerage disposal of hydrogen-3 and carbon-14 is appropriate because it will not pose an unreasonable risk to the public.

The Environmental Protection Agency and at least one other commenter observed that the information presented in the preliminary value/impact analysis was not sufficient to support the need to raise the limits for hydrogen-3 and

carbon-14 which can be discharged to sanitary sewers. The EPA also stated that the increased health risk from the release of hydrogen-3 and carbon-14 in the quantities now in use appears to be very low.

The Commission believes that raising the limits for release of hydrogen-3 and carbon-14 to the sanitary sewerage systems will benefit perhaps 20 30 NRC licensees. The dollar savings in radioactive waste burial capacity are not known; however, even some savings in the cost of medical research and some savings in radioactive waste burial capacity are a direct benefit to the public and should not be foregone because they are difficult to quantify.

Finally, the Environmental Protection Agency noted that the preliminary value/impact analysis gave estimates of the individual doses which might result from the proposed changes: however. they suggested that the final value/ impact analysis include an assessment of the collective dose commitment. The preliminary value/impact analysis included a brief treatment of the collective dose commitment. The final value/impact analysis includes a more rigorous treatment of this question. However, the conclusion of the final value/impact analysis has not changed. Basically, the value/impact analysis concludes this rulemaking is non-substantive and insignificant from the standpoint of environmental impact.

Clarifications

Several commenters requested clarification on the boundaries of the rule change. Does the term liquid scintillation media include the vials containing the media? Does the term animal tissue include organs or fluids which may have been removed from the carcasses for analysis."

The regulation in 10 CFR 20.306(a) applies to the disposal of liquid scintillation media of 0.05 microcuries or less of hydrogen-3 or carbon-14 per gram of medium. Licensees may dispose of liquid scintillation media containing this
concentration of hydrogen-3 or carbon-14 without regard to its radioactivity. Scintillation vials themselves are not radioactive. Rather, it is the scintillation media remaining in the vials that contains the radioactivity. The rule covers that material. Therefore, it would be permissible to dispose of the used vials along with the media.

Similarly, the regulation in 10 CFR 20.30B(b) applies to the disposal of animal tissue of 0.05 microcuries or less of hydrogen-3 or carbon-14 per gram of tissue averaged over the weight of the entire animal, whether the tissue (or organ) is ultimately removed from the carcass or not. However, the regulation does not apply to either the radioactive chemicals before they are administered to the animals or to the animal feces or urine or contaminated

bedding.

Finally, some commenters asked if the rule change would permit incineration of the scintillation media and animal carcasses without obtaining permission from NRC via a license amendment. The answer is, yes, liquid scintillation media and animal carcasses may be incinerated without a license amendment to the extent permitted by applicable non-radioactive waste disposal regulations. This rule is being made effective on March 11, 1981, because it relieves licensees from restrictions.

Authority: Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code the following amendments to Title 10, Chapter I. Code of Federal Regulations, Part 20, are published as a document subject to codification.

-END-