

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

Standards for Protection Against Radiation

AGENCY: Nuclear Regulatory Commission,

ACTION: Proposed rule.

SUMMARY: The NRC is considering 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. 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 proposed regulations, the licensee may dispose of specified concentrations of these materials without regard to their radioactivity. The NRC is also considering amending its regulations to raise the annual limits for disposal of hydrogen-3 and carbon-14 by release to the sanitary sewerage system. The proposed rule changes would conserve waste burial capacity that is already in short supply.

DATE: Comment period expires November 24, 1980.

Note: Comments received after the expiration date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before that date.

ADDRESSES: Interested persons are invited to submit written comments and suggestions for consideration on the proposed amendments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of the preliminary value/impact analysis and 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 preliminary value/impact analysis are available from John R. Cook at the phone number and address listed below.

FOR FURTHER INFORMATION CONTACT: John R. Cook, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301-427-4240).

SUPPLEMENTARY INFORMATION: 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 radioisotopes 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 and shipped 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 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 trace 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 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 system. The annual limit for release to the sanitary sewerage system is found in 10 CFR 20.373 and is limited to a total of 1 curie of all radionuclides per year for each licensee. This proposed rule would

raise the limit for hydrogen-3 to 5 curies per year and the limit for carbon-14 to 1 curie per year. This change would result in a negligible addition to the level of these radioisotopes already present in 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, none 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 (§§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 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 rain water percolation in the trenches.

The three 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. 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 rulemaking would 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 would 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 would also allow the disposal by release to a sanitary sewerage system 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 authorizes disposal of liquid scintillation media (e.g., toluene) into the sanitary sewerage system.

Because the amount of hydrogen-3 and carbon-14 that could be released to the environment as a result of this rulemaking is very small, and because calculations employing conservative assumptions indicate the dose to any exposed individual is likely to be much less than 1 millirem per year, the Commission believes that the rulemaking would have little adverse impact from a radiological health standpoint.

The rule would essentially remove any NRC restrictions on the disposal of liquid scintillation media and animal carcasses. It would 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 preliminary value/impact analysis prepared by the NRC staff to support the proposed 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. The preliminary value/impact analysis indicates that the action is non-substantial and insignificant from the standpoint of environmental impact. 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 would save almost one-half million cubic feet of radioactive waste burial capacity annually, or half of that used for radioactive waste not related to nuclear power generation and its supporting fuel cycle.

In summary, the proposed amendments concerning the disposal of tracer levels of hydrogen-3 and carbon-14 in liquid scintillation media and animal carcasses would be appropriate because: (a) the proposed amendments would 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 would 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 Commission has decided that a 45 day comment period for this rulemaking is appropriate because the potential radiological impacts are small and there is a shortage of available burial ground capacity.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of Title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 20 is contemplated.

1. In § 20.301, paragraph (c) is revised to read as follows:

§ 20.301 General requirement.

* * * * *

(c) As provided in § 20.303 or § 20.304, applicable respectively to the disposal of licensed material by release into sanitary sewerage systems or burial in soil, or in § 20.306 for disposal of specific wastes, or in § 20.106 (Radioactivity in effluents to unrestricted areas).

2. In § 20.303, paragraph (d) is revised to read as follows:

§ 20.303 Disposal by release into sanitary sewerage systems.

* * * * *

.1) The gross quantity of licensed and other radioactive material, excluding hydrogen-3 and carbon-14, released into the sewerage system by the licensee does not exceed one curie per year. The quantities of hydrogen-3 and carbon-14 released into the sanitary sewerage system may not exceed 5 curies per year for hydrogen-3 and 1 curie per year for carbon-14. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section.

3. § 20.305 is revised to read as follows:

§ 20.305 Treatment or disposal by incineration.

No licensee shall treat or dispose of licensed material by incineration except for materials listed under § 20.306 or as specifically approved by the Commission pursuant to §§ 20.106(b) and 20.302.

4. A new § 20.306 is added to read as follows:

§ 20.306 Disposal of specific wastes.

(a) Any licensee may dispose of the following licensed material without regard to its radioactivity:

(1) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of medium, used for liquid scintillation counting; and


(2) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of animal tissue averaged over the weight of the entire animal; provided however, tissue may not be disposed of under this section in a manner that would permit its use either as food for humans or as animal feed.

(b) Nothing in this section, however, relieves the licensee of maintaining records showing the receipt, transfer, and disposal of such byproduct material as specified in § 30.51 of this chapter.

(Sec. 81, 161b, Pub. L. 83-703, 68 Stat. 935, 948, as amended (42 U.S.C. 2111, 2201), Sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841)).

Dated at Washington, DC, this 2d day of October, 1980.

For the Nuclear Regulatory Commission


Samuel J. Chilk
Secretary of the Commission