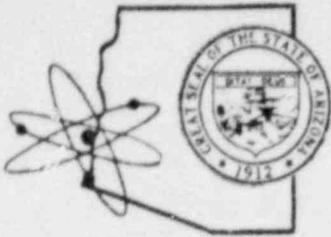


DOCKET NUMBER PR 20
PROPOSED RULE 45FR67018

(48)



STATE OF ARIZONA
RADIATION REGULATORY AGENCY

925 S. 52nd Street, Suite 2 • Tempe, AZ 85281
Phone: (602) 255-4845

October 31, 1980



U. S. Nuclear Regulatory Commission
Docketing and Service Branch
Washington, D.C. 20555

Dear Sirs:

The following comments are forwarded related to "Changes of Regulations on Disposal of Radioactive Wastes Resulting from Medical Research":

1. Five curies/year of tritium to the sewer is very conservative if NRC would consider appropriate daily and monthly concentration limits.
2. With issuance of this change, de minimum levels for ordinary hospital trash should be considered. The amount of ³H and ⁴C that could be released is about 50,000 pci/gram or 50 uci/liter.
3. The toluene may end up being "incinerated" in automobiles. This probably reduces the dose, but needs to be assessed.
4. The possibility of several licensees utilizing the same sewer system and/or the same incinerator needs to be assessed.
5. There should be de minimus levels for other isotopes such as Iodine-125 and Technicium-99 commonly found in hospital trash systems.

If you have questions, please do not hesitate to contact our office.

Sincerely,

Charles F. Tedford
Director

JG:CFT:cap

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Acknowledged by card... 11/5/80

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

OFFICE OF PUBLIC AFFAIRS, REGION V
1990 N. California Boulevard, Suite 202, Walnut Creek, Ca. 94596

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FOR IMMEDIATE RELEASE
(Mailed - October 9, 1980)

NOTE TO EDITORS: This information was released yesterday by NRC Headquarters in Washington, D.C., and is forwarded for your information.

NRC CONSIDERS CHANGES TO REGULATIONS ON DISPOSAL OF
RADIOACTIVE WASTES RESULTING FROM MEDICAL RESEARCH

The Nuclear Regulatory Commission is considering changing its regulations to eliminate the requirement that licensed biomedical research laboratories and hospitals send animal carcasses and vials containing tracer amounts of certain radioactive materials to radioactive waste burial grounds. Under the amended regulations, licensees would be able to dispose of these materials without regard to their radioactivity.

The licensed materials covered by the changes would be:

- 1) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of liquid scintillation media, 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.

Tracer amounts of hydrogen-3 and carbon-14 are added to chemical compounds or experimental drugs to study the drugs' behavior in research animals. After the drug containing radioactive material is administered to an animal, a sample from the animal's urine, blood or body tissue is combined with an organic solvent--such as toluene--in a small vial to make a "liquid scintillation medium." The vial is placed in a "liquid scintillation counter," which measures the amount of radioactivity in the sample. The radioactivity amount can be used to derive the needed information on the behavior of the drug. The vials are used once and then are ready for disposal.

Research laboratories and hospitals throughout the country are using between 84 and 159 million vials per year, which represents 200 to 400 thousand gallons of liquid scintillation media. Disposal of this waste in radioactive waste burial grounds requires approximately 400 thousand cubic feet of storage space at a cost of over \$13 million per year.

"more"

Animals are also used 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 compound behaves. The animal carcasses containing tracer quantities of hydrogen-3 and carbon-14 require about 80 thousand cubic feet of space in radioactive waste burial grounds at a cost of about \$3 million per year.

Liquid scintillation media and animal carcasses containing tracer quantities of hydrogen-3 and carbon-14 together constitute the largest volume of radioactive medical waste. Liquid scintillation media make up approximately 43 percent of the total volume of radioactive waste in burial grounds that is not related to nuclear power generation and its supporting fuel cycle. Animal carcasses constitute about 9 percent of the non-nuclear-power-related radioactive waste in burial grounds.

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 indicate the dose to any exposed individual is likely to be much less than 1 millirem per year, the Commission believes that the changes to the regulations would have little adverse impact on the environment from a radiological health standpoint. The proposed rule changes would conserve waste burial capacity that is already in short supply.

The amendments would also raise the limit for the amount of hydrogen-3 and carbon-14 that may be released to sanitary sewerage systems. Under present NRC regulations, a licensee may release a total of 1 curie of all radioactive materials in this manner. Raising the limit for hydrogen-3 to 5 curies per year and for carbon-14 to 1 curie per year as would be permitted by the proposed revisions to the regulations, would be a negligible addition to the amount of radioactivity already present in the natural environment.

Interested persons are invited to submit written comments on the proposed amendments, which are to Part 20 of the Commission's regulations, to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by November 24, 1980 (45 days after publication in the Federal Register on October 8, 1980).

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Any Comments?

address to: