

FD-20
99-20- (45 FR 67018)



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

SEP 29 1980

MEMORANDUM FOR: Joseph M. Felton, Director
Division of Rules and Records, ADM

FROM: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

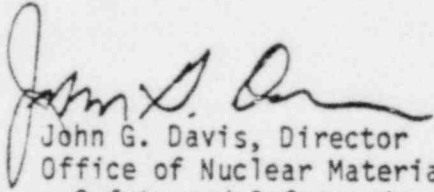
SUBJECT: IMPLEMENTATION OF COMMISSION ACTION ON SECY-80-410,
"PROPOSED AMENDMENTS OF 10 CFR PART 20 ON DISPOSAL OF
CERTAIN H-3 AND C-14 WASTES"

We have been informed that on September 19, 1980, the Commission approved publication of the enclosed Federal Register Notice concerning certain low-level radioactive wastes.

Please implement the Commission's action by having the enclosed notice signed by Mr. Chilk and published in the Federal Register for a 45-day public comment period.

Appropriate Congressional Committees are being informed of this action concurrently by the Office of Nuclear Material Safety and Safeguards.

Also enclosed are three copies of the "PRELIMINARY VALUE/IMPACT STATEMENT OF AMENDMENTS TO 10 CFR 20 FOR DISPOSAL OF BIOMEDICAL AND AQUEOUS WASTES." Please request the Docketing and Service Branch, SECY, to place the documents in the Public Document Room simultaneously with forwarding the notice to the Office of the Federal Register.


John G. Davis, Director
Office of Nuclear Material
Safety and Safeguards

Enclosures: As stated

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

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 20.303 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 sewage 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.

* * * * *

(d) 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 day of , 1980.

For the Nuclear Regulatory Commission

Samuel J. Chilk
Secretary of the Commission

PRELIMINARY VALUE/IMPACT STATEMENT
OF AMENDMENTS TO 10 CFR 20
FOR DISPOSAL OF BIOMEDICAL AND AQUEOUS WASTES

I. The Proposed Action

- A. Description - The principal current method for disposal of biomedical and aqueous waste containing tracer quantities of hydrogen-3 and carbon-14 under NRC regulations is to ship them to commercial radioactive waste disposal grounds. The amendments to 10 CFR 20 will allow licensees to dispose of these wastes without regard to their radioactivity. However, they will be subject to other federal, state and local regulations governing any other toxic properties of the materials. Thus the proposed amendments would allow licensees to dispose of certain biomedical and aqueous wastes using commercial or municipal refuse collection services, incineration, landfill, or other means, to the extent permitted by applicable, non-radioactive waste disposal regulations.
- B. Need for the Proposed Action - Byproduct material licensees are required under 10 CFR 30.41 to transfer licensed material only to persons licensed to receive byproduct material. About 51% of this waste is comprised of liquid scintillation vials, animal carcasses and aqueous fluids containing tracer quantities of hydrogen-3 or carbon-14. Present disposal in commercial radioactive waste disposal grounds necessitates the transportation of these wastes, generally over great distances, and at great expense to the licensees. The transportation of these materials poses a difficult materials

handling problem because the scintillation medium is both flammable and carcinogenic, and the decaying carcasses, in addition to being unsanitary, generate methane gas which can explode or otherwise rupture waste containers. Moreover, these wastes consume scarce waste disposal grounds capacity, which would otherwise be used for radioactive wastes truly requiring burial. Finally, should the waste sites be closed for any reason, there could be a prompt and serious interruption of biomedical research activities throughout the nation.

10 CFR 20 should be amended to eliminate the problems involved in the transport or storage of these wastes and the unnecessary consumption of scarce waste disposal grounds capacity.

C. Value/Impact of the Proposed Action

1. NRC Operations - The proposed amendments to 10 CFR 20 would reduce the impact on NRC resource requirements. The licensing staff would not need to consider licensing amendments, such as incineration, for alternatives to commercial disposal of these materials. It would also reduce the number of waste packages that need to be inspected. The amendments would require no new reporting, new funding, nor time or personnel resources once the rule is published.

2. Other Government Agencies - NRC Agreement States could make similar amendments to their regulations in order to extend the benefits to licensees in those states. The value to the Agreement States would be similar to that of the NRC.
3. Licensees - The primary value of the amendments would be to biomedical research institutions, and to a lesser extent, nuclear medicine laboratories. Other types of laboratories might also receive some benefits. The value results from a reduction of cost for disposal of scintillation vials, animal carcasses, and certain aqueous fluids. Current costs for packing materials, transportation and disposal of these wastes as now required are estimated below (does not include cost of licensee labor or overhead):
- a. For Liquid Scintillation Counting Waste (LSCW) (see Attachment 1 for documentation of biomedical waste statistics):
- Total low-level waste (LLW) shipped to a burial site = $3 \times 10^6 \text{ ft}^3/\text{year}$
- Approximately 30% of LLW is so-called institutional waste:
- $$3 \times 10^6 \text{ ft}^3/\text{year} \times 0.3 = 9 \times 10^5 \text{ ft}^3/\text{year}$$
- About 43% of institutional waste is due to disposal of liquid scintillation vials or fluids:
- $$9 \times 10^5 \text{ ft}^3/\text{yr} \times .43 \approx 3.9 \times 10^5 \text{ ft}^3/\text{year}$$
- A 55 gallon drum will hold about 7.35 ft^3 ; thus:
- $$3.9 \times 10^5 \text{ ft}^3/\text{year} \div 7.35 \text{ ft}^3/\text{drum} \approx 53,000 \text{ drums/year}$$

We estimate the average cost of packaging materials, transportation, and burial of a drum of liquid scintillation waste to be at least \$250.

Therefore, the estimated total cost for annual shipments of liquid scintillation waste to disposal grounds is:

$$53,000 \text{ drums/year} \times \$250/\text{drum} = \$13,250,000.$$

- b. For Animal Carcasses - About 9% of institutional waste is comprised of animal carcasses, tissues, and other biological matter associated with biomedical research.

From the above:

$$9 \times 10^5 \text{ ft}^3/\text{year} \times 0.09 = 81,000 \text{ ft}^3/\text{year}$$

or

$$8.1 \times 10^4 \text{ ft}^3/\text{year} \div 7.35 \text{ ft}^3/\text{drum} = 11,020 \text{ drums of biological waste.}$$

We estimate the average cost of packaging materials, transportation and burial of a drum of biological waste to be at least \$300.

Thus, the estimated total cost for annual shipments of biological waste to disposal grounds is:

$$11,020 \text{ drums/year} \times \$300/\text{drum} = \$3,305,000.$$

- c. For aqueous waste - No data are available to estimate the number of drums of adsorbed or solidified aqueous waste shipped to disposal grounds. It is believed, however, that in revising the 1 curie limit contained in 10 CFR 20.303 to 5 curies and 1 curie for hydrogen-3 and carbon-14, respectively, some benefit would accrue to institutions engaged in biomedical research. Industrial facilities would be little affected by the proposed amendments to increase the sanitary sewerage limits for hydrogen-3 and carbon-14. The scale of research using hydrogen-3 and carbon-14 tracers in industrial facilities is generally small and is unlikely to lead to many industrial licensees' research activities taking advantage of the rule change. There are, however, some industrial licensees (e.g., manufacturers of labeled compounds, luminous source manufacturers, etc.) who might benefit from the rule change. However, they are relatively small in number and, therefore, would not contribute significantly to the total environmental release nor realize substantial cost savings.

To summarize, the proposed amendments would save approximately \$16,000,000 in waste disposal costs; most of these savings would be realized in biomedical research. New costs would be incurred, however, in the disposal of these wastes through conventional means. Since conventional disposal is much cheaper than transport and burial at radioactive waste disposal grounds, it is estimated that the net savings would be about \$13,000,000.

- d. Disposal Grounds - The amendments would result in a loss of revenue due to the elimination of most shipments from biomedical facilities. These shipments currently account for 15% of annually buried waste and therefore are not an economic necessity. The amendment would prolong site use at a time when disposal capacity is in short supply.
4. Public/Environmental - The decrease in costs to biomedical facilities for waste disposal would allow these resources to be used in productive areas of biomedical investigation for the public benefit. There should be no increased costs to the public resulting from these amendments. The public would also benefit through the continued operation of biomedical facilities in the event of an embargo at disposal grounds and from the ability of the grounds to accept additional volume of other types of radioactive waste.

The effects of the amendments on the environment were analyzed. Estimated exposures are as follows:

With respect to alternative disposal methods for the liquid scintillation medium and animal carcasses, we have concluded that incineration would provide the greatest radiation impact on the environment.

To calculate the dose to the maximum exposed individual, an individual living near a very large biomedical research facility was considered (see Attachment 2). It was assumed the facility generated about 275 mCi of tritium and 75 mCi of carbon-14 in liquid scintillation and carcass wastes combined each year, and that all these wastes were incinerated. For the dose due to inhalation, it was assumed the individual remained at a distance of 40 meters from the incinerator stack for the entire year. Using inhalation rates, dose conversion factors and other data contained in Regulatory Guide 1.109, "Calculation of Annual Doses to Man From Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR Part 50, Appendix I," the doses to the total body (for hydrogen-3) and bone (for carbon-14) were calculated. The results estimate the dose from the hydrogen-3 to be 0.01 mrem/year and 0.04 mrem/year from carbon-14.

For the dose from ingestion, it was assumed the individual subsisted completely on food grown or water located at a distance of 40 meters from the incinerator stack. Using ingestion parameters from a model developed by Oak Ridge National Laboratory, the doses to the whole body (critical organ for hydrogen-3) and bone marrow (critical organ for carbon-14) were calculated, yielding a dose of about 0.03 mrem/year from hydrogen-3 and 5.3 mrem/year from carbon-14.

Thus, the maximum individual exposure calculated to result from this disposal scenario is on the order of 5 mrem per year, or about 1/20 of the dose considered to be natural background radiation. Furthermore, the assumptions used greatly exaggerate any actual dose to a member of the public, which would likely be much less than 1 mrem/year, considerably less than EPA's 4 mrem drinking water standard for hydrogen-3.

Disposal of these wastes via municipal solid waste was also considered. Appendix D of an NRC sponsored Study of Consumer Products Containing Radioactive Material developed a calculational technique for examining the impacts of disposal of consumer products into municipal refuse. Consideration of this analysis with respect to municipal refuse disposal of liquid scintillation media or animal carcasses leads to the conclusion that the dose from this disposal alternative would be minor relative to that from incineration.

With respect to increasing the annual sewerage release limit for hydrogen-3 and carbon-14 to 5 and 1 curies respectively, the maximum ingestion dose was calculated for an individual subsisting on the nearest potable water supply downstream from the sewerage treatment plant. It was assumed a very large user of hydrogen-3 and carbon-14 was located immediately upstream from the treatment plant, and that the five curies of hydrogen-3 and curie of carbon-14 were discharged at a constant rate over a one year period. Using the dose conversion factor and other data

from Regulatory Guide 1.109, the doses to the whole body (critical organ for hydrogen-3) and bone (critical organ for carbon-14) were calculated. Assuming the facility was located in a metropolitan area, the dose from hydrogen-3 contributed by the rule change* would be about 0.005 mrem/year and 0.03 mrem/year for carbon-14. The actual dose to a member of the public would be much less than 1 mrem, again less than EPA's 4 mrem standard for drinking water for hydrogen-3. Since the amount of hydrogen-3 and carbon-14 released to the environment due to the proposed amendments is orders of magnitude less than natural levels, and since the probable dose to exposed members of the public is less than 1 mrem per year, it is concluded that the proposed amendments have no significant impact on the environment.

This rule will not result in a change in the total quantity of hydrogen-3 and carbon-14 as waste. It is estimated that under the new rule the resulting health effects will be much less than one per year and will not be substantially different than the health effects resulting from disposal of these materials under present rules.

- D. Decision on the Proposed Action - The proposed amendments should be published in the Federal Register for public comment.

II. Technical Approach

A. Technical Alternatives

Alternative 1: Rely on conventional waste disposal methods for scintillation vials and animal carcasses less than

*Assuming a background level of 287 pCi/liter of hydrogen-3 in water, the total volume of water used in this calculation would contain approximately 240 Ci of hydrogen-3 from natural causes and weapons fallout.

0.05 $\mu\text{Ci/gm}$ in hydrogen-3 or carbon-14 concentration, subject to regulations regarding disposal of non-radioactive waste.

Provides immediate elimination of long-distance transportation hazards with no significant increase in risks to the public or licensees. Alternative waste management systems (e.g., collection services or sewerage system) are already established. Greatly reduced cost to licensees and to a lesser extent to NRC would result from this alternative.

Alternative 2: Establish new disposal sites that would accept biomedical waste.

There is some difficulty in keeping the three existing disposal grounds open due to a variety of problems, including public concern. It is unlikely that any new sites will be operational soon. Even if new sites are established, the same problems would exist except there would be some increase in disposal capacity.

Alternative 3: As an interim solution, require licensees to store biomedical waste on site.

This alternative would require a change in the license of a great many affected licensees, resulting in considerable expenditure of time and personnel resources for both licensees and the NRC. Would expose licensees to the hazards similar to those involved in the transport of the wastes, i.e., fire and carcinogenic hazard of scintillation vials, and sanitation and explosion hazard from decaying carcasses. This alternative does not solve the problem because the long half-lives of hydrogen-3 (12 years) and carbon-14 (5,730 years) require the wastes to be disposed of eventually.

Alternative 4: Cease biomedical research and other activities involving uses of hydrogen-3 and carbon-14.

This alternative would be unacceptable to the public, who derive great benefit from biomedical research and other activities involving hydrogen-3 and carbon-14.

Alternative 5: Wait for exemptions as part of the general rule for low-level waste (10 CFR Part 61).

Relief is needed now. The rule will not be an effective regulation until 1982 at the earliest.

- B. Decision on Technical Approach - The proposed amendments should be published in the Federal Register for public comment, relying on the technical approach described in Alternative 1.

III. Procedural Approach

A. Procedural Alternatives

Alternative 1: Amend 10 CFR 20 through (1) addition of a new Part 20.306 to allow disposal of scintillation vial medium and animal carcasses containing less than 0.05 $\mu\text{Ci/gm}$ of hydrogen-3 or carbon-14 subject to other applicable disposal regulations; and (2) the modification of 10 CFR 20.303 to allow disposal of aqueous waste containing hydrogen-3 or carbon-14 to a maximum of 5 curies per year for hydrogen-3 and 1 curie per year for carbon-14.

This alternative provides immediate relief from the current storage and transportation problems associated with biomedical waste. It assures continued operation of facilities using hydrogen-3 and carbon-14 in the event of an embargo at disposal grounds. This alternative can also be implemented at little or no cost to either NRC, its licensees, or the public. Environmental impacts from a radiation standpoint will be negligible.

Alternative 2: Allow licensees to apply for license modifications (e.g., incineration) permitting the disposal of biomedical and aqueous wastes. This alternative would require months, even years, before all the license modifications could be reviewed and approved. Therefore, it does not eliminate the storage and transport hazard of biomedical waste, nor does it assure all facilities will remain operational in the event of disposal ground embargoes. This alternative would require expenditure of licensee resources to prepare the license modifications and NRC resources to review the modifications. For many licensees there is little if any option under the present regulation other than sending the waste to burial grounds. For example, many licensees located in metropolitan areas have state or local laws prohibiting incineration, and they are not located upon sites in which they can bury their own wastes.

- B. Decision on Procedural Approach - The procedural approach described in Alternative 1 should be proposed for public comment.

IV. Statutory Considerations

- A. NRC Authority - The amendments fall under the authority and safety requirements of the Atomic Energy Act of 1954, as amended.

- B. Need for NEPA Statement - The proposed action is non-substantive and insignificant from a standpoint of environmental impact and therefore does not require either an environmental impact statement or a negative declaration.
- V. Relationship to Other Existing or Proposed Regulations on Policies - No conflicts or overlaps with requirements promulgated by other agencies are foreseen. The amendments are consistent and in accord with the Commission's regulations and policies.
- VI. Summary and Conclusions - The proposed amendments to 10 CFR 20 on biomedical and aqueous waste disposal should be published in the Federal Register for public comment.

BIOMEDICAL WASTE STATISTICS

The total activities and volumes of biomedical waste here were derived from average concentrations reported in various laboratories, from biomedical supply houses, NUREG/CR-1137, and data files of NRC's Division of Waste Management. An early NUS Corporation report entitled "Preliminary State-By-State Assessment of Low-Level Radioactive Wastes Shipped to Commercial Burial Grounds" reported much higher total activities than those estimated here. The data in this report are now believed, however, to overestimate the quantities of biomedical wastes, and the report is being revised by the authors to reflect a reassessment of biomedical waste shipments.

The following sections document or show the derivation of biomedical waste statistics used in this paper. The sections included are:

- I. Summary of Annual U. S. Low Level Radioactive Waste Volume
- II. Estimated Total Volume of Liquid Scintillation Counting (LSC) Media Waste
- III. Reported Radioactivity Concentrations and Estimated Total Activities for Liquid Scintillation Counting Media
- IV. Estimated Annual Activity of Hydrogen-3 and Carbon-14 Contained in Biological Waste
- V. Estimated Total Radioactivity of Hydrogen-3 and Carbon-14 in The Liquid Scintillation Counting (LSC) and Biological Wastes Generated Annually in the United States

I. SUMMARY OF ANNUAL U.S. LOW LEVEL RADIOACTIVE WASTE VOLUME

	Annual Volume		Per Cent of Total Low Level Waste	Reference
	55 gal. drums*	cubic feet		
Total Low Level Waste	408,200	3,000,000	100.0	1
Institutional Waste **	122,400	900,000	30.0	1
Liquid Scintillation Counting Waste	53,060	390,000	12.9	2
Biological Waste***	11,020	81,000	2.7	2

*Volume of a 55-gallon drum = 7.35 ft³

**Institutional waste as used here includes low level radioactive waste not generated by nuclear power plants or the supporting nuclear fuel cycle facilities

***Biological waste as used here includes animal carcasses and tissues from biomedical research facilities

References:

1. NRC Division of Waste Management: "General Description of Low Level Waste Generated for Commercial Disposal in the United States," October 1979.
2. NUREG/CR-1137, Institutional Radioactive Wastes, published October 1979, Table 3.13, p. 44, discussion p. 67.

II. ESTIMATED TOTAL VOLUME OF LIQUID SCINTILLATION COUNTING (LSC) MEDIA WASTE

The exact volume of LSC media waste is unknown, but the range of the volume can be estimated.

The lower range value is based on the annual production of liquid scintillation vials and an estimate of the number of liquid scintillation counters in the U.S. Mr. C. Killian of New England Nuclear Corporation, the largest producer of scintillation vials in this country, has estimated that in total 7,000 vials are produced for each of 12,000 counters each year. Hence:

$$7,000 \text{ vials/counter/yr} \times 12,000 \text{ counters} = 84 \times 10^6 \text{ vials/yr}$$

Assuming each vial contains 10ml:

$$84 \times 10^6 \text{ vials/yr} \times 10\text{ml/vial} = 840,000 \text{ liters/yr or}$$

$$221,800 \text{ gallons of liquid scintillation media per year}$$

For the upper range value, the total number of LSC vials disposed of annually in the U.S. is calculated from the estimated number of LSC waste drums and the maximum number of vials disposed of per drum. Using the previous estimate of 53,060 drums of LSC waste and assuming 3,000 vials per drum (NUREG-1137, p. 67 suggests 2200-3000 vials/drum), we have:

$$53,060 \text{ drums/year} \times 3,000 \text{ vial./drum} = 159 \times 10^6 \text{ vials/year}$$

Again, at 10ml/vial:

$$159 \times 10^6 \text{ vials/yr} \times 10\text{ml/vial} = 1,590,000 \text{ liters/yr or}$$

$$419,800 \text{ gallons of liquid scintillation media per year}$$

The volume of liquid scintillation media is thus estimated to be between 221,800 and 419,800 gallons per year.

III. REPORTED RADIOACTIVITY CONCENTRATIONS
AND ESTIMATED TOTAL ACTIVITIES
FOR LIQUID SCINTILLATION COUNTING MEDIA

	Concentration $\mu\text{Ci/vial}$	Reference	Total Activity in Curies per Year Assuming:	
			84×10^6 vials/yr	159×10^6 vials/yr
Hydrogen-3	0.004	1	0.3 Ci/yr	0.6 Ci/yr
	0.070	2	5.9	11.1
	0.019	3	1.6	3.0
	0.100	4	8.4	15.9
	0.280	5	23.5	44.5
	0.001	6	0.8	1.6
Carbon-14	0.00015	1	0.13 Ci/yr	0.2 Ci/yr
	0.00021	2	0.18	0.3
	0.00019	3	0.16	0.3
	0.00080	5	0.67	1.3
	0.00010	6	0.08	0.159
	0.00017	7	0.14	0.3

References:

1. Personal communication with Dr. Robert Hamilton, Chief of Radiation, Physics Dept. of V.A. Medical Center, Bronx, New York, and Professor of Nuclear Medicine of Albert Einstein College of Medicine. Also includes data from Columbia Presbyterian Medical Center, New York. August 1980.
2. NUREG/CR-1137, Institutional Radioactive Wastes, published October 1979, pp. 58 and 60.
3. Personal communication with Roger Broseus, National Institutes of Health, August 1980. Reported concentrations are an average.
4. Captain W. H. Briner, NRC consultant. Concentration given is an upper limit.
5. Personal communication with Leland Cooley, Radiation Safety Office, University of Maryland, August 1980. This is a high concentration estimated average from reviewing data from 100 LSC drums.
6. Personal communication with C. Killian, Environmental Control Director, New England Nuclear, August 1980.
7. NUREG/CR-0028, Institutional Radioactive Wastes, published March 1978, p. 49.

IV. ESTIMATED ANNUAL ACTIVITY OF HYDROGEN-3 AND CARBON-14 CONTAINED IN BIOLOGICAL WASTE

NRC's Waste Management Division recently sponsored a study of waste categories which the prime contractor, Dames & Moore, subcontracted to Leland Cooley at the University of Maryland.* Based on a survey of large waste generating institutions believed to account for approximately 21% of the biological waste in the United States, the study estimated the annual activity contained in animal carcasses, tissues, excreta, and bedding, combined, to be 3.23 curies of hydrogen-3 and 1.26 curies of carbon-14.

The 21% share of total U. S. biological waste estimated for these large institutions may underestimate their actual contribution by 10% or more. If the 21% figure is assumed, however, the annual U. S. biological waste would be calculated to contain 15.4 Ci of hydrogen-3 and 6.0 Ci of carbon-14.

*Unpublished data

V. ESTIMATED TOTAL RADIOACTIVITY OF HYDROGEN-3 AND CARBON-14
 IN THE LIQUID SCINTILLATION COUNTING (LSC) AND BIOLOGICAL WASTES
 GENERATED ANNUALLY IN THE UNITED STATES

	<u>Waste</u>	<u>Total Activity in Ci/year Assuming Average or Maximum Concentrations</u>	
		<u>Range or Average</u>	<u>Maximum</u>
Hydrogen-3	LSC	11.0 - 16.0	44.5
	Biological	<u>15.4</u> <u>15.4</u>	<u>15.4</u>
		24.6 - 31.4	59.9
		28.0	60.0
Carbon-14	LSC	0.3	1.3
	Biological	<u>6.0</u>	<u>6.0</u>
		6.3	7.3

Value/Impact Statement
Attachment 2

Disposal of Liquid Scintillation Media and Animal
Carcasses Containing Tracer Levels of H-3 or C-14
Without Regard to Their Radioactivity:

Estimates of Maximum Potential Radiation Dose to an Individual

The radiation dose commitment to an individual due to disposal of liquid scintillation counting wastes and animal carcasses containing H-3 and C-14 is calculated in this report. Both inhalation and ingestion pathways are considered in the calculations. Since H-3 and C-14 are low energy beta emitters, the external exposure from these two sources will not be considered. The dose commitment is calculated according to the following basic equation.

$$D = C \times U \times DCF$$

Where D is the dose commitment to a given organ of an individual, in mrem/yr; C is the concentration of a nuclide in the media, in pCi/liter; U is the usage factor unit in liter/yr; and DCF is the dose conversion factor in units of

$$\frac{\text{mrem}}{\text{pCi}} \quad \text{or} \quad \frac{\text{mrem}}{\text{yr}} \quad \text{per} \quad \frac{\text{Ci}}{\text{m}^3}$$

(I) Inhalation Mode

Dose commitment to an individual is calculated based on the assumption that the individual inhaled contaminated effluents produced by combustion of animal carcasses and liquid scintillation counting wastes containing H-3 and C-14. The calculation is also based on the following assumptions:

- (1) H-3 and C-14 enter the human body by inhalation in the form of HTO and CO₂ respectively.
- (2) Source terms: total activity* to be burned over a year for H-3 and C-14 is 0.275 Ci and 0.075 Ci respectively.

* Represents the annual activities in the liquid scintillation wastes and animal carcasses generated in large research and medical institutions in this country as determined in an NRC in-house survey.

- (3) The nearest resident is located about 10-40 meters from the incinerator. The air concentration once exiting the incinerator will be reduced by an atmospheric dilution factor of 10^{-3} sec/m^3 when it reaches the nearest resident.
- (4) The incinerator is operated 2000 hours per year.

Dose From Inhalation

$$D = C \times U \times DCF$$

Where D = Dose commitment due to inhalation by an individual remaining at a distance of 40 meters downwind from the incinerator for the entire year;

C = Concentration of radioactive effluents at 10-40 meters from the incinerator, and is calculated as follows:

$$C = \frac{\text{Activity (Ci)}}{\text{incinerator operation time (hrs)}} \times X/Q \frac{\text{sec}}{\text{m}^3} \times \frac{\text{hrs}}{3600 \text{ sec}}$$

For H-3:

$$= \frac{0.275 \text{ Ci}}{2000 \text{ hrs}} \times 10^{-3} \frac{\text{sec}}{\text{m}^3} \times \frac{\text{hrs}}{3600 \text{ sec}}$$

$$= 3.8 \times 10^{-11} \frac{\text{Ci}}{\text{m}^3} = 3.8 \times 10^1 \frac{\text{pCi}}{\text{m}^3}$$

For C-14:

$$= \frac{0.075 \text{ Ci}}{2000 \text{ hrs}} \times 10^{-3} \frac{\text{sec}}{\text{m}^3} \times \frac{\text{hrs}}{3600 \text{ sec}}$$

$$= 1.0 \times 10^{-11} \text{ Ci/m}^3 = 1.04 \times 10^1 \text{ pCi/m}^3$$

Breathing rate, U:

$$U = 8000 \text{ m}^3/\text{yr} \times \frac{\text{yr}}{8760 \text{ hr}} \times \frac{2000 \text{ hr}}{\text{yr}} = 1.83 \times 10^3 \text{ m}^3/\text{yr}$$

DCF: Dose conversion factors for inhalation dose were obtained from Regulatory Guide 1.109.

DCF for H-3 (total body as critical organ) is $1.58 \times 10^{-7} \frac{\text{mrem}}{\text{pCi}}$

DCF for C-14 (bone as critical organ) is $2.3 \times 10^{-6} \frac{\text{mrem}}{\text{pCi}}$.

Dose due to inhalation of H-3

$$D_{\text{H-3}} = 3.8 \times 10^1 \frac{\text{pCi}}{\text{m}^3} \times 1.83 \times 10^3 \frac{\text{m}^3}{\text{yr}} \times 1.58 \times 10^{-7} \frac{\text{mrem}}{\text{pCi}}$$

$$= 0.01 \text{ mrem/yr (total body)}$$

Dose due to inhalation of C-14:

$$D_{\text{C-14}} = 10.4 \frac{\text{pCi}}{\text{m}^3} \times 1.83 \times 10^3 \frac{\text{m}^3}{\text{yr}} \times 2.3 \times 10^{-6} \frac{\text{mrem}}{\text{pCi}}$$

$$= 0.04 \text{ mrem/yr (bone)}$$

(II) Ingestion Mode

The estimated dose due to dietary and drinking water intake of H-3 and C-14 from incineration of biomedical wastes is also calculated under assumptions 2 and 3 listed for the inhalation mode. In addition, it is assumed the food and drinking water are in equilibrium with the

specific activity of H-3 in the atmosphere, and the specific activity of C-14 in human tissue is equal to the average steady-state value in the atmosphere. The methodology of the calculation is presented fully in ORNL-4992, "A Methodology for Calculating Radiation Dose from Radioactivity Release to the Environment."

A. Dose from ingestion:

$$D = C \times DCF$$

Where D = Dose in mrem/yr due to dietary and drinking water intake;

C = Annual average concentration of radioactivity at 10-40 meters from the incinerator resulting from the incineration of 0.275 Ci H-3 and 0.075 Ci of C-14 annually.

For H-3:

$$\begin{aligned} C &= \frac{0.275 \text{ Ci}}{\text{yr}} \times 10^{-3} \frac{\text{sec}}{\text{m}^3} \times \frac{\text{hrs}}{3600 \text{ sec}} \\ &= \frac{0.275 \text{ Ci}}{8760 \text{ hr/yr}} \times 10^{-3} \frac{\text{sec}}{\text{m}^3} \times \frac{\text{hrs}}{3600 \text{ sec}} \\ &= 8.7 \times 10^{-12} \text{ Ci/m}^3 \end{aligned}$$

For C-14:

$$\begin{aligned} C &= \frac{0.075 \text{ Ci}}{8760 \text{ hr/yr}} \times 10^{-3} \frac{\text{sec}}{\text{m}^3} \times \frac{\text{hrs}}{3600 \text{ sec}} \\ &= 2.2 \times 10^{-12} \text{ Ci/m}^3 \end{aligned}$$

DCF = Dose conversion factor in mrem yr/Ci/m³, annual dose rate per unit air concentration of H-3 or C-14 radioactivity at the point of interest (data taken from ORNL-4992):

For H-3, with total body as critical organ:

$$DCF = 3.68 \times 10^9 \frac{\text{mrem}}{\text{yr}} / \text{Ci/m}^3$$

For C-14, with bone marrow as critical organ:

$$DCF = 2.22 \times 10^{12} \frac{\text{mrem}}{\text{yr}} / \text{Ci/m}^3$$

Dose due to ingestion of H-3:

$$\begin{aligned} D &= 3.68 \times 10^9 \text{ mrem/yr/Ci/m}^3 \times 8.7 \times 10^{-12} \text{ Ci/m}^3 \\ &= 0.03 \text{ mrem/yr to total body} \end{aligned}$$

Dose due to ingestion of C-14:

$$\begin{aligned} D &= 2.22 \times 10^{12} \frac{\text{mrem}}{\text{yr}} / \text{Ci/m}^3 \times 2.4 \times 10^{-12} \text{ Ci/m}^3 \\ &= 5.33 \text{ mrem/yr to bone marrow} \end{aligned}$$

B. Dose due to drinking the contaminated water

The dose is calculated to an individual who subsists on the potable water supply from the sewerage treatment plant. It is further assumed that a very large user of hydrogen-3 and carbon-14, located in a metropolitan area and upstream from the treatment plant, discharged 5 curies of H-3 and 1 curie of C-14 into the sewer over a period of one year. The doses to the critical organ of an individual were calculated by using dose conversion factors given in NRC Regulatory Guide 1.109.

Dose from Ingestion

$$D = C \times U \times DCF$$

D = Dose in mrem/yr due to ingestion of contaminated water

C = Potable water concentration of H-3 and C-14. It is assumed that the discharged 5 Ci of H-3 and 1 Ci of C-14 was diluted by a volume of 600×10^6 gallons water at releasing point of the water treatment plant. 600×10^6 gallons of water represents the total water that is being handled each day by a large city's water treatment facility.

For H-3:

$$C = \frac{5 \text{ Ci}}{600 \times 10^6 \text{ gal}} = 2.2 \times 10^3 \frac{\text{pCi}}{\text{liter}}$$

For C-14:

$$C = \frac{1 \text{ Ci}}{600 \times 10^6 \text{ gal}} = 4.4 \times 10^2 \frac{\text{pCi}}{\text{liter}}$$

U = Water consumption rate per year = 730 liter/yr

DCF = Dose conversion factors for ingestion

$$\text{For H-3: } 1.05 \times 10^{-7} \frac{\text{mrem}}{\text{pCi}} \quad (\text{Total body as critical organ})$$

$$\text{For C-14: } 2.8 \times 10^{-6} \frac{\text{mrem}}{\text{pCi}} \quad (\text{Bone as critical organ})$$

Dose due to ingestion of H-3:

$$D = 2.2 \times 10^3 \frac{\text{pCi}}{\text{liter}} \times 730 \text{ liter/yr} \times 1.05 \times 10^{-7} \frac{\text{mrem}}{\text{pCi}}$$

$$= 1.68 \times 10^{-1} \text{ mrem/yr}$$

$$= 0.17 \text{ mrem/yr (Total body)}$$

Dose due to ingestion of C-14:

$$D = 4.4 \times 10^2 \frac{\text{pCi}}{\text{liter}} \times 730 \frac{\text{liter}}{\text{yr}} \times 2.8 \times 10^{-6} \frac{\text{mrem}}{\text{pCi}}$$

= 0.9 mrem/yr (Bone)