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Office Memorandum • UNITED STATES GOVERNMENT

TO : T. H. Johnson, Director, Division of Research, DATE: February 1, 1954
Washington

FROM : S. R. Sapirie, Manager, Oak Ridge Operations 726743

SUBJECT: AMENDMENT OF RADIOISOTOPE DISTRIBUTION REGULATIONS TO PROVIDE
FOR GENERAL RADIOLOGICAL HEALTH-SAFETY STANDARDS

SYMBOL: OI:CEC

Enclosed, in accordance with your memorandum of January 4 to Dr. Aebersold on "General Radiological Health-Safety Standards," is a staff paper for submission to the Commission proposing that radioisotope distribution regulations be amended by the addition of general radiological health-safety standards applicable to users of AEC distributed radioisotopes.

These standards are based upon recommendations of the National Committee on Radiation Protection. We consider the proposed standards to be practicable. Minimal requirements are set forth, and no attempt has been made to specify the exact means of complying with the standards. The methods or procedures to be used in complying with the regulations are left to the discretion of the user inasmuch as several optional procedures, equally efficacious, may be available in any particular case to assure minimum radiation exposure. Further, elasticity is achieved by recognizing that under certain conditions exposure in excess of 300 millirad/week may be necessary. Exceptions are provided for such emergencies or unforeseen circumstances.

It is our understanding that Representative Sterling H. Cole, upon learning that health-safety standards were in draft stage, requested that an information copy of the standards be forwarded to him at an early date. We shall appreciate your making a copy of the proposed standards available to Representative Cole.

This office recommends that the enclosed staff paper be forwarded to the Commission for approval. Distribution of information copies of this staff paper is being made to members of the Isotopes Division's Advisory Committee on Isotope Distribution. Consideration should also be given to furnishing information copies to the National Committee on Radiation Protection and other groups particularly concerned with radiological safety.

S. R. Sapirie
for S. R. Sapirie

CC: R. W. Cook, Washington
Assistant General Counsel, ORO
J. C. Bugher, Washington

ISOTOPE PROGRAM -3

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ATOMIC ENERGY COMMISSION
AMENDMENTS TO RADIOISOTOPE DISTRIBUTION REGULATION

Report by the Manager of Oak Ridge Operations

THE PROBLEM

1. To consider amendment of the Commission's regulations governing radioisotope distribution so as to provide for general radiological health-safety standards.

SUMMARY

2. The radioisotope distribution regulations do not contain radiological health-safety standards having general application to the use, possession, storage, and disposal of radioisotopes. The Director, Isotopes Division, has been authorized by regulation to "establish for individual cases such standards and instructions governing the possession and use of radioisotopes as he may determine to be necessary or desirable to protect health or to minimize danger from hazards to life or property." The amendments proposed by this report, (Appendix "B") will establish radiological health-safety standards of general scope applicable to all radioisotope users. In the interests of health-safety such standards should be adopted by the AEC and published in the Federal Register. Such standards in the Federal Register may be amended readily. To be effective the standards should include specific tolerance values. Publication of such standards will not have an unfavorable effect on future state regulations and actions. Regulations will complement and not replace present measures to promote safety through education.

STAFF JUDGMENTS

3.

RECOMMENDATION

4. That the Atomic Energy Commission:

a. Approve publication in the Federal Register of the amendments to the radioisotope distribution regulation substantially in the form set forth in Appendix "B";

b. Note that the General Manager will arrange for such publication in conformity with the procedure which allows for a thirty-day period after initial publication for receipt of public comments or objections;

c. Note that, if after the thirty-day period no substantial changes are indicated, the General Manager will arrange for publication of the amendments in final form. If substantial changes are indicated, they will be submitted to the Commission for approval; and

d. Note that the Joint Committee on Atomic Energy will be informed of these actions by appropriate letter.

LIST OF ENCLOSURES

Appendix "A"

Background and Discussion

Appendix "B"

Proposed Amendment of Part 30 -- Radioisotope Distribution (10 CFR 30).

APPENDIX "A"

BACKGROUND

5. The Atomic Energy Act of 1946 in Section 5 (c)(2) authorizes the Atomic Energy Commission to distribute by-product materials for research or development activity, medical therapy, industrial uses, or such other useful applications as may be developed. The AEC is directed, however, not to distribute any by-product materials to any applicant and to recall any distributed materials from any applicant "... who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such materials in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor."*

6. In Section 12(a) of the Act, the AEC is further authorized to "... establish by regulation or order such standards and instructions to govern the possession and use of fissionable and by-product materials as the Commission may deem necessary or desirable to protect health or to minimize danger from explosions and other hazards to life or property."

7. In line with the AEC's statutory authority, the Isotopes Division drafted regulations, for Commission approval, governing the procurement, delivery, possession, use, transfer (including export) and disposal of radioisotopes. These regulations appeared in a staff paper (AEC 398) which the Commission approved on January 25, 1951. This paper included a footnote, which now appears in the Code of Federal Regulations at the end of the radioisotope regulations, that "... it is the Commission's intention to publish at a later date and incorporate in this part appropriate health

*emphasis added

and safety standards." Paragraph 16 C. of the paper states that: "...Safety standards to accompany and supplement the instructions will comply with the intent of the Atomic Energy Act that the Commission establish, where necessary or desirable, measures for the protection of health and prevention of damage to property."

8. The plan to publish health and safety standards has been discussed with the Advisory Committee on Isotope Distribution at several of its meetings. At the meeting on March 23, 1950, there was general agreement that published health safety standards for radioisotope users were desirable and "... would serve as a convenient, authoritative reference for radioisotope users and persons generally, and as a guide for the activities of local supervising officials. Industrial applicants, in particular, prefer to accept specific regulations rather than mere recommendations which would not be binding."

The Committee passed the following recommendation:

"The Committee recommends establishment and publication in the Federal Register of standards and instructions governing the procurement, delivery, possession, use and disposal of radioisotopes allocated by the AEC in order to protect health and minimize hazards to life and property."

9. The Committee at meeting of March 26, 27, 1951, agreed that the growing entry of industry into the radioisotopes field increased the need for definite guides and standards with respect to a user's obligations to the public. The following recommendation was passed:

"The Committee approves publication in the Federal Register of health and safety standards based on the firm recommendation of the International Committee on Radiation Protection."

In addition, industrial leaders have expressed a desire for federal regulations pertaining to radioisotopes. The Stanford Research Institute reports in Industrial Uses of Radioactive Fission Products that, "Need for a standardized, simplified, and generally acceptable safety code for handling radioactivity is widely expressed in industry ... Most companies emphasized that it is much easier to live within a set of government regulations if these regulations are known, understandable, and practicable..."

10. Regulations governing the possession, use, transfer, and disposal of radioisotopes were published in the Federal Register (16 F.R. 3251, April 13, 1951) and are codified in 10 CFR 30. A statement of authority of the Director, Isotopes Division, and an administrative appeals procedure for reviewing orders of the Director were published in the Federal Register July 25, 1953, the latter to be codified as § 30.90 of the radioisotope distribution regulations. Further amendments, primarily establishing criteria for the issuance of Authorizations for Radioisotope Procurement, were published in the Federal Register on January 14, 1954 (19 F.R. 243). The Director, Isotopes Division, is authorized to establish radiological health-safety standards for individual cases only. Existing regulations do not contain radiological health-safety standards of a general nature or scope.

DISCUSSION

11. A number of questions have been raised recently regarding the necessity and desirability of publishing in the Federal Register radiological health-safety standards applicable to radioisotope users. These questions may be summarized as follows:

- (1) Should the AEC adopt official radiological health-safety standards for users of AEC distributed radioisotopes?

(2) If official standards are adopted, is it necessary that they appear in the Federal Register?

(3) Could such AEC standards appearing in the Federal Register be amended readily?

(4) Should the AEC standards include specific tolerance values or merely refer to NBS handbooks?

(5) Would such AEC standards have an unfavorable effect on future state regulations and actions?

12. The AEC should adopt official radiological health-safety standards for users of AEC distributed radioisotopes. During the past seven years the AEC has not officially adopted health-safety standards applicable to the use of radioisotopes. In the early phases of the radioisotope distribution program, promulgation of standards was not practicable since there was no general agreement on tolerance values, permissible contamination levels, etc. The National Committee on Radiation Protection in recent years, however, has issued recommendations on safe operating procedures, tolerance values, etc. The Isotopes Division, on its own initiative, has adopted the recommendations of the NCRP (published in NBS Handbooks) and recommended that radioisotope users follow them. Radioisotope users are referred to NBS Handbooks in correspondence and articles on health-safety appearing in "Isotopics." The Division, however, has no one official document which can be presented to users as official AEC standards.

13. The need for legally enforceable radiological health-safety standards governing the use of radioisotopes has been apparent for some time. The increasing use of such materials in industry and field operations and the use of larger quantities of radioactive material have pointed up the need for such

standards. Representatives of the Isotopes Division visit approximately 400 institutions each year. Unsafe practices and procedures have been found in a number of instances. Employees of one radiographer, as an example, routinely and continuously received in excess of 300 mr/week, receiving as high as 3300 mr/week in some instances, with the average being about 600 mr/week. In another case, contamination levels in a laboratory were 200 times the maximum permissible contamination level according to NCRP standards. Strontium 90 contamination levels in another laboratory averaged 20 mr/hr or more. A Technician was handling Strontium 90-filled wire with unprotected hands (30 mr/hr at 0.5 inch from the wire). Another institution, despite several requests from both the Isotopes Division and its own safety officers, failed to account for a loss of 500 mc of Cobalt 60 and to decontaminate areas where multiple small pieces of cobalt had been spilled. In all of these instances it was necessary to issue individual, formalized instructions (orders) before the unsatisfactory conditions were corrected.

14. The Isotopes Division, in promoting safe practices relies for the most part upon persuasion and education. In most instances, recommendations that radioisotope users abide by the standards of the NCRP have been sufficient. However, since these standards have not been made official by the AEC, some radioisotope users have indicated that they would not follow these standards if they are merely recommendations. In several instances, including those enumerated in paragraph 13, advice and recommendations proved inadequate. As indicated, it was necessary for the Isotopes Division to issue formalized instructions establishing standards on an individual basis, allow a reasonable time to elapse, inspect again to see if the deficiency or unsafe practices had

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been corrected. Establishing standards on an individual basis is time consuming and results in considerable delay before corrective measures can be achieved. This case-by-case approach also appears unfair to the user involved, inasmuch as the standards thus established do not necessarily apply to other users; no one is bound to follow any particular safety practices. This is very important in certain fields such as industrial radiography where the competition is pronounced. General radiological health-safety standards, applicable to all radioisotope users, would help correct this undesirable situation.

15. If the Commission should find it necessary to recall radiomaterials in the interests of public health and safety, it would be administratively desirable to take such legal action on the basis of regulations published in the Federal Register or upon notification personally served on the radioisotope user prior to the time of the questionable action. The availability of standards as the basis of the action taken is desirable to minimize possible charges of arbitrary or capricious action and other legal objections stemming from the usual rules and customs for advising the party acted against of the requirements he should have taken prior to taking punitive measures. A hazardous situation might develop requiring immediate Commission action, not permitting the delay involved in establishing standards on an individual basis.

16. The increasing use of radioisotopes by industry has pointed up the need for publishing regulations binding upon all users. Traditionally, industry desires to know the ground rules before it invests in a new field. Businessmen also prefer to operate under established rules so that all competitors are on an equal basis. The Stanford Research Institute found an expressed desire for radiation standards among industrial leaders; the Isotopes Division has encountered the same desire. For example, the General Electric Company has expressly requested the AEC to take some action to establish minimum safety standards which can be enforced. Industrial firms with long range interest in

the field of radioisotope utilization wish to avoid unfavorable publicity and public alarm which could result from marginal operators who would sacrifice safety for greater profit.

17. If AEC radiological safety standards are adopted by the AEC they should be published in the Federal Register. The Federal Register has been designated as the central repository for all federal regulations. Section 3(a) of the Administrative Procedure Act provides that;

"(a) Rules. Every agency shall separately state and currently publish in the Federal Register(3) substantive rules adopted as authorized by law and statements of general policy or interpretations formulated and adopted by the agency for the guidance of the public, but not rules addressed to and served upon named persons in accordance with law.

No person shall in any manner be required to resort to organizations or procedure not so published."

Assuming that the AEC does adopt official standards, they should be published in accordance with law as regulations in the Federal Register. Unless this is done, it is possible that the standards or regulations may be disregarded by those persons whom the agency seeks to bind.

18. AEC standards appearing in the Federal Register may be amended readily. Ordinarily regulations are published thirty days before the effective date of the regulation. This 30 day period may be shortened by the agency "upon good cause found." If the public interest so requires, AEC regulations could be amended immediately. Thus, more restrictive figures could be published without delay. If a specific published figure should be considered too stringent, it could be amended without the 30 days notice inasmuch as this would be a "relieving restriction" and not subject to § 4(c) of the Administrative Procedure Act.

19. AEC standards should include specific tolerance values and not merely refer to NBS handbooks. An attempt to incorporate NBS handbooks into the regulations by reference only would be impracticable for enforcement purposes and possibly subject to criticism from a legal viewpoint. A statement in the Federal Register that all radioisotope users shall comply with such standards as may be established by the National Committee on Radiation Protection might well be construed as an ineffectual attempt by the AEC to redelegate to a group outside the AEC regulatory authority which has been expressly delegated to the AEC by Congress.

20. Of course, an administrative body with rule-making authority may "adopt" recommendations of other bodies or persons and incorporate them into the agency's regulations. There does not appear to be a single instance in which an agency has attempted to "adopt" a binding rule by reference in the Federal Register to the source such as an NBS handbook. Regulations which merely referred users to handbooks would, in effect, require radioisotope users to consult both the Federal Register and various and sundry handbooks in order to find the laws or rules which bind them. This would be a backward step and result in confusion similar to that which prevailed before enactment of the Federal Register Act and Administrative Procedure Act when agencies merely published their rules in pamphlets and handbooks. The Federal Register is intended as a central repository for federal regulations and it should not be necessary to go outside the Register to find the policies and rules of a federal agency.

21. An attempt to adopt handbooks or similar material also has other disadvantages. It may be subject to criticism on the grounds that changes can and will be made in the handbooks without a prior 30 days publication

in the Federal Register, thus avoiding the notice of the proposed change, and the opportunity to be heard. The issuance of authoritative explanations or interpretations would be difficult, due to uncertainties as to whether the agency issuing the handbook, or the AEC, is the final authority as to the proper interpretation. This would be accompanied by constant questions as to whether recommendations, suggestions, opinions or advice expressed in the handbooks had been adopted as such by AEC, or whether the AEC intended to convert them into positive requirements. It is difficult to see how advisory guides, couched in language showing clearly that they are no more than that, can be understood or enforced as "standards".

22. NBS handbooks will continue to be of value in the isotopes program since they set forth radiological safety procedures and practices and methods of achieving compliance with standards. AEC standards will be a skeletonized summary of mandatory requirements. The exact means of complying with these standards is left to the user, and in these respects many handbooks, pamphlets, articles, etc., are desirable references. Although the handbooks are of great informational value, they are not an adequate substitute for regulations.

23. Publication of AEC standards will not adversely affect future state regulations and actions. It would be advantageous to radioisotope users, including AEC contractors, if federal health safety regulations were established which the states could use as a model, rather than independently enacting regulations that may be unduly restrictive. During recent months several proposed drafts of state legislation have come to the attention of the Isotopes Division. These drafts are considerably longer, more detailed, and more highly restrictive than the health-safety standards in Appendix "B".

24. One draft of state regulations would require users to obtain licenses in addition to the AEC Authorization and obtain permission from the

state before disposing of radioactive wastes, irrespective of quantity involved. Further, the proposed regulation states that, "a radiation hazard exists at any place where a person may be exposed to the rays from radioactive materials, where he may come in physical contact with radioactive materials, or where airborne radioactive materials are present." Apparently a radiation hazard would exist if one wore a luminous dial watch or worked with a microcurie of Carbon 14. The proposed regulation would permit a maximum permissible concentration in air of 1×10^{-7} uc/ml for beta-gamma emitters. This value would be unduly stringent for some radioisotopes and too liberal for others. The NCRP would permit 2×10^{-5} uc/ml for H³ and 2×10^{-10} uc/ml for Sr 90 and Y 90. A proposed draft from another state consists of 17 pages of outline only. Among other provisions, smoking, eating, use of cosmetics, the bringing of combs, handbags, etc., into hazardous areas would be prohibited. The washing of hands would be regulated. A third draft defines "sealed container" in such a manner as would include any bottle or other container of radioactive material if the bottle had a tight lid.

25. Publication of AEC standards at this time may go a long way in avoiding an end result of state codes lacking both uniformity and practicability. In the final analysis, of course, the steps which the states will take in this field rests with the several states irrespective of Federal action. Nevertheless, it appears highly desirable that the AEC publish standards which the states could use as a guide.

26. Regulations will complement and not replace present measures to promote safety through education. Representatives of the Isotopes Division will continue to visit radioisotope users, not only to assure compliance with regulations, but to assist the users wherever possible in establishing safe operating practices in the use of radioisotopes. Orders based on regulations

will be issued only when a user has demonstrated that he will not comply with standards or recommendations. Recall of material or cancellation of shipments probably would be the most serious punitive action the AEC would need to take in enforcing its regulations and then only on willful violators. The AEC will continue to rely heavily upon education, assistance, and cooperation with the great majority of users, reserving formalized instructions and orders for the recalcitrant few. Cooperation with state health departments and other groups which contribute to radiological health safety, will be continued.

APPENDIX "B"

UNITED STATES

ATOMIC ENERGY COMMISSION

PROPOSED AMENDMENT OF PART 30 - RADIOISOTOPE DISTRIBUTION (10 CFR 30)

Notice is hereby given that adoption of the following rules is contemplated. All interested persons who desire to submit comments and suggestions for consideration by the General Manager of the Atomic Energy Commission in connection with the proposed rules shall send them to the General Manager, United States Atomic Energy Commission, Washington 25, D. C., within 30 days after publication of this notice in the Federal Register.

Part 30 of Radioisotope Distribution Regulations (10 CFR 30) is hereby amended as follows:

1. Section 30.2 is amended by addition of the following definition:

30.2 (o) "Rad" is the unit of absorbed dose of ionizing radiation and is 100 ergs per gram. In the case of dose to personnel this means 100 ergs per gram of average soft tissue.

2. Section 30.51 is amended to read:

30.51 Overexposure Records. Where an exposure of a person to radioisotopes in excess of 300 mr/week or 300 mrad/week is believed to have occurred, the occurrence and its observed effect upon the overexposed person shall be recorded in detail and filed with the general records. (See also 30.85 (b) (2)).

3. Section 30.61 is amended to read:

30.61 Other Action

(a) Any person who violates any provision of these regulations, or who, in connection with these regulations, willfully conceals a material fact or furnishes false information to the Commission, may be prohibited by the Commission from making or obtaining further deliveries of

radioisotopes or using, possessing, or storing them and may be required to return to the Commission all radioisotopes remaining on hand.

(b) Whoever willfully violates, attempts to violate, or conspires to violate, any provision of these regulations shall, upon conviction thereof, be punished by a fine of not more than \$5,000.00 or by imprisonment for not more than two years, or both, except that whoever commits such an offense with intent to injure the United States or with intent to secure an advantage to any foreign nation shall, upon conviction thereof, be punished by a fine of not more than \$20,000.00 or by imprisonment for not more than twenty years, or both.

4. Section 30.85, 30.86, 30.87 and 30.88, reading as follows, are added:

30.85 General Radiological Health-Safety Standards

Each person who possesses or uses radioisotopes shall institute adequate safeguards, records,* radiological safety procedures, and take such other appropriate measures as may be necessary to assure that such radioisotopes are used, stored, transported, or otherwise handled, in conformity with the radiological health safety standards set forth below:

(a) Maximum Permissible Exposure. Radioisotopes shall be used, stored, transported, or otherwise handled, in such a manner that the total external and/or internal exposure of any part of a person's body to all types of radiation emitted by radioisotopes shall be held at the lowest practicable level and, except as hereinafter permitted, shall not exceed in any one week any value or limitation set forth in Table I. (Exposure to any combination of radiation set forth in Table I shall not exceed the biological equivalent of the values set forth for X and gamma rays).

*Overexposure records are to be kept in accordance with Section 30.51.

TABLE I
 MAXIMUM PERMISSIBLE EXPOSURE LIMITS PER WEEK

Type of Radiation	Roentgen		rad*	
	Hands and Forearms	Other Parts of the Body	Hands and Forearms	Other Parts of the Body
X-Ray & Gamma Rays	1.0**	0.3**		(external exposure)
Beta Rays			1.5***	0.5*** (internal exposure)
Alpha Rays				0.015****
Fast Neutrons (2 Mev)			0.1	0.03
Thermal Neutrons (.02 ev)			0.2	0.06

** As measured in free air

*** Applies to exposure in the basal layers of the epidermis corresponding to a depth of 7 mg/cm².

**** Considered internal hazard only

(b) Exceptions to Paragraph (a), Table I

(1) Medical Therapy and Medical Research. The limits of radiation exposure set forth in paragraph (a), Table I, do not apply to the intentional exposure of patients or human subjects for purposes of medical diagnosis and/or therapy or medical research authorized by the Commission;

(2) Emergencies or Unforeseen Circumstances. If emergent or unforeseen circumstances should require or justify the exposure of a limited number of persons in excess of the limits of paragraph (a), Table I,

* Definition: The rad is the unit of absorbed dose and is 100 ergs per gram. In measuring exposure of personnel this means 100 ergs per gram of average soft tissue.

in the interest of public health and safety, or the health and safety of other personnel, or otherwise in the public interest, the limits of radiation exposure set forth in paragraph (a), Table I, shall not apply: PROVIDED, however, that such persons thus exposed shall be removed from further radiation exposure for an appropriate period of time; PROVIDED FURTHER, that the Isotopes Division of the AEC shall be notified promptly of any radiation exposure received during any one week in excess of two times any value or limitation of paragraph (a), Table I.

(c) Radiation Monitoring and Surveying Instruments.

(1) When radioisotopes are used or stored so that an exposure rate per hour to personnel exceeds 7.5 milliroentgen due to X or gamma rays or 12.5 millirad due to beta particles or 0.75 millirad due to fast neutrons or 1.5 millirad due to thermal neutrons, survey instruments having suitable sensitivity shall be on hand or immediately available for periodical surveying of radiation fields. When radioisotopes are used, except in permanently sealed sources, such that surface contamination is probable, suitable survey instruments shall be on hand or immediately available for measuring contamination as defined in paragraph (g)(1) of this section.

(2) All persons working within or having frequent occasion to enter any area where the radiation dosage rate per hour exceeds that stated in paragraph (c)(1) above or having any occasion to enter a field or radiation having a dosage rate per hour exceeding 10 times these values shall be supplied with and shall wear an appropriate radiation detection device such as film badge, film ring, pocket or other ionization chamber or electroscope.

(3) Instruments used for the measurement and detection of radiation shall be maintained in proper calibration. The film used in radiation detection devices shall be processed and interpreted under conditions that will insure proper calibration.

(d) Instructions to Personnel.

Persons working with or in proximity to radioisotopes shall be adequately instructed concerning handling of radioactive materials, proper use of all radiation detecting devices and monitoring instruments furnished for their protection, and procedures to be followed if radiation exposure should exceed permissible limits.

(e) Radiation Caution Signs and Labels.

(1) All areas or sites in which radioisotopes are used or stored shall be clearly and conspicuously marked with a durable sign or signs, such sign to bear a conventional radiation symbol (magenta or yellow background). The limits or boundaries of those areas in which the exposures exceed the values stated in paragraph (c)(1) above shall be posted with warning signs employing the words "Caution: Radioactive Materials. Do not remain on any one day within or near this area in excess of the following time and distance limitations: _____ minutes (or hours) at _____ inches (or feet)." Within these areas additional caution signs should be posted which specify the limits of time and distance such that persons working within or having occasion to enter these areas will not, in following such precautions, receive radiation exposure in excess of that stated in Table I. An area caution sign shall not be required for devices which incorporate a sealed source provided the exposures outside of the device do not exceed the values stated in paragraph (c)(1) and the device is properly labeled in accordance with Section 30.80 (e)(2) or 30.81 (e)(2).

(f) Storage and Use of Radioisotopes

(1) Radioisotopes shall be stored in a protective container or inclosure of suitable materials except when such radioisotopes are in use. Radioisotopes stored outside of buildings or in accessible areas shall be kept in locked containers. Great care shall be exercised to prevent loss or theft of radioisotopes or devices containing radioisotopes. Entry of unauthorized persons to operating and storage areas where radioisotopes are present shall be prevented or discouraged by appropriate measures such as locking of access doors, roping off of areas, and posting of signs.

(2) Radioactive gases and radioactive volatile materials shall be stored in gas-tight containers. When such gases, volatile materials, radioactive droplets, or dust particles, are encountered in the work in such a way or in such quantities as to create hazardous contamination in the air, the material shall be handled in appropriate closed or ventilated systems, or appropriate protective respiratory equipment such as respirators or self supplied pressure masks shall be used.

(3) When contamination of air in the laboratory or work area is a probability, suitable equipment for monitoring purposes shall be on hand or immediately available.

(g) Contaminated Materials

(1) Clothing, equipment, working areas, and other materials and surfaces shall be considered contaminated when their activity exceeds the following:

(i) 500 dis/min for alpha emitting radioisotopes*

(ii) 1.0 mrad/hr for beta and/or gamma emitting radioisotopes

other than those listed in (iii) below.*

(iii) 0.1 mrad/hr for Sr 90, Ca 45, Zr 95, Bi 210*

*Average values as measured in a small volume of air (in a thin layer) above any 2 square inch area.

(2) Appropriate procedures shall be instituted and followed to protect employees and other persons from contact with contaminated materials before disposal.

(3) Contaminated clothing and bedding shall not be released to public laundries.

(h) Contamination of Air and Water.

For purposes of limiting and controlling continuous intake of radioactive materials by inhalation, ingestion, or absorption through the skin, the maximum concentration of radioisotopes in the air and drinking water at locations in which employees or other persons may be present or have access thereto shall not exceed concentrations which, if inhaled or ingested continuously, will cause exposure to any part of the body in excess of 0.3 rad/week. The information presented in Table 2 represents the present state of knowledge on the maximum permissible concentration of radioisotopes in air and water and should thus serve as a guide in complying with the regulations in this section.

(i) Medical Therapy.

Patients receiving high dosage radioisotope therapy shall be hospitalized or suitably confined until the total body content of administered radioactive material has been reduced to a maximum of 50 millicuries. The physician responsible for administration of the high dosage radioisotope therapy shall inform either the patient or the patient's family concerning radiation safety precautions when home care is required. The physician shall inform the patient's family physician, if any, and the hospital staff concerning health safety precautions required for hospital care, and in addition, shall inform the hospital pathologist regarding special precautions that might be necessary in handling the body if death should occur

TABLE II

MAXIMUM PERMISSIBLE CONCENTRATION OF RADIOISOTOPES IN AIR AND WATER

Radioisotope	Column I Microcuries Per Milliliter of Air	Column II Microcuries Per Milliliter of Water
A ⁴¹	5×10^{-7}	5×10^{-4}
Ag ¹⁰⁵	10^{-5}	2
Ag ¹¹¹	3×10^{-5}	4
Am ²⁴¹	3×10^{-11}	10^{-4}
As ⁷⁶	2×10^{-6}	0.2
At ²¹¹	3×10^{-10}	2×10^{-6}
Au ¹⁹⁸	1×10^{-7}	3×10^{-3}
Au ¹⁹⁹	2.5×10^{-7}	7×10^{-3}
Ba ¹⁴⁰ + La ¹⁴⁰	6×10^{-8}	2×10^{-3}
Be ⁷	4×10^{-6}	1
C ¹⁴	5×10^{-7}	4×10^{-3}
Ce ¹⁴⁵	3×10^{-8}	5×10^{-4}
Cd ¹⁰⁹ + Ag ¹⁰⁹ m	7×10^{-8}	7×10^{-2}
Co ¹⁴⁴ + Pt ¹⁴⁴	7×10^{-9}	4×10^{-2}
Cl ³⁶	4×10^{-7}	2×10^{-3}
Cm ²⁴²	2×10^{-10}	9×10^{-4}
Ce ⁶⁰	10^{-6}	2×10^{-2}
Ce ⁵¹	8×10^{-6}	0.5
Cs ¹³⁷ + Ba ¹³⁷ m	2×10^{-7}	1.5×10^{-3}
Cu ⁶⁴	6×10^{-6}	8×10^{-2}
Ba ¹⁵⁴	6×10^{-9}	3×10^{-2}
P ¹⁸	10^{-4}	0.9

TABLE II (contd.)

Radioisotope	Microcuries Per Milliliter of Air	Microcuries Per Milliliter of Water
Fe ⁵⁵	6×10^{-7}	4×10^{-3}
Fe ⁵⁹	1.5×10^{-8}	1×10^{-4}
Ga ⁷²	3×10^{-6}	9
Ge ⁷¹	4×10^{-5}	9
H ³ (HTO or H ₂ O)	2×10^{-5}	0.2
Ho ¹⁶⁶	3×10^{-6}	23
I ¹³¹	3×10^{-9}	3×10^{-5}
Ir ¹⁹⁰	7×10^{-7}	10^{-2}
Ir ¹⁹²	5×10^{-8}	9×10^{-4}
K ⁴²	2×10^{-6}	1×10^{-2}
La ¹⁴⁰	10^{-6}	1
Lu ¹⁷⁷	5×10^{-6}	24
Mn ⁵⁶	3×10^{-6}	0.15
Mo ⁹⁹	2×10^{-3}	14
Na ²⁴	2×10^{-6}	8×10^{-3}
Nb ⁹⁵	4×10^{-7}	4×10^{-3}
Ni ⁵⁹	2×10^{-5}	0.25
P ³²	1×10^{-7}	2×10^{-4}
Pb ²⁰³	6.5×10^{-6}	0.1
Pd ¹⁰³ + Rh ¹⁰³	7×10^{-7}	1×10^{-2}
Pm ¹⁴⁷	2×10^{-7}	1

TABLE II (contd.)

Radioisotope	Microcuries Per Milliliter of Air	Microcuries Per Milliliter of Water
Po ²¹⁰ (sol.)	2×10^{-10}	3×10^{-5}
Po ²¹⁰ (insol.)	7×10^{-11}	-
Pz ¹⁴³	7.5×10^{-7}	0.4
Rb ⁸⁶	4×10^{-7}	3×10^{-3}
Re ¹⁸³	8×10^{-6}	8×10^{-2}
Rh ¹⁰⁵	10^{-6}	1.5×10^{-2}
Rn ²²² + Dr	10^{-8}	2×10^{-6}
Ru ¹⁰⁶ + Rh ¹⁰⁶	3×10^{-8}	0.1
S ³⁵	10^{-6}	5×10^{-3}
Se ⁴⁶	7×10^{-8}	0.4
Sm ¹⁵¹	10^{-8}	0.2
Sn ¹¹³	6×10^{-7}	0.2
Sr ⁸⁹	2×10^{-8}	7×10^{-5}
Sr ⁹⁰ + Y ⁹⁰	2×10^{-10}	8×10^{-7}
Tc ⁹⁶	3×10^{-6}	3×10^{-2}
Te ¹²⁷	10^{-7}	3×10^{-2}
Te ¹²⁹	4×10^{-8}	10^{-2}
Tb ²³⁴	6×10^{-7}	3
Tm ¹⁷⁰	5×10^{-8}	0.25×10^{-1}
V ⁴⁸	10^{-6}	0.5
Xe ¹³³	4×10^{-6}	4×10^{-3}
Xe ¹³⁵	2×10^{-6}	1×10^{-3}
Y ⁹¹	4×10^{-8}	0.2
Zn ⁶⁵	2×10^{-6}	6×10^{-2}
All other beta or gamma emitters	10^{-9}	10^{-7}
All other alpha emitters	5×10^{-10}	10^{-7}

30.86 Disposal of Radioisotopes as Wastes

(a) Disposal into Air and Water. Except as hereinafter provided, radioisotopes shall be discharged into the air or water (including streams, rivers, ponds, and lakes - for disposal in the ocean see sub-section (d) below) only in such quantities and at such intervals that the maximum concentration of radioactivity in these media shall not exceed (at points where human consumption may result) concentrations which if ingested or inhaled continuously will cause exposure to any part of the body in excess of 0.3 rad/week.*

(b) Disposal into Public Sewers

(1) If radioisotopes are discharged into public sewers, the following precautions shall be observed.

(i) The radioisotope shall be in a form readily soluble in water.

(ii) The radioactive material discharged shall not exceed 1 millicurie of Sr 90 or Po 210 or 10 millicuries of other isotopes per day per million gallons of municipal sewage effluent per day.

(iii) Following disposal of radioactive material the disposal sink faucet shall be allowed to run at full flow for approximately 10 minutes or the commode adequately flushed.

(iv) Iodine 131 and Phosphorus 32 shall not be disposed of at a rate exceeding 100 millicuries per day per million gallons of municipal sewage effluent per day.

*Special efforts should be made to keep values well below those listed in Table 2.

(v) The radioisotope user shall provide reasonable radiological safety precautions during work on laboratory or institutional drains through which radioisotopes are discharged.

(c) Disposal by Burial in Soil

(1) Radioisotopes shall not be buried in the soil unless:

(i) The burial area is devoid of edible plant life; has soil, topographic and geologic characteristics not conducive to pronounced erosion or leaching; is properly marked and protected against unauthorized entry.

(ii) The burial depth is not less than 4 feet.

(iii) The dosage rate at the surface of the ground does not exceed 0.3 roentgen per week.

(2) Radioisotopes having a half-life greater than 180 days shall not be buried in quantities per cubic foot of burial ground greater than 0.1 millicurie of Strontium 90 or 0.1 millicurie of Polonium 210, or 10 millicuries of other isotopes, except upon prior approval by the Commission.

(3) Limits set forth in (2) above shall not apply to radioisotopes that have been diluted and homogeneously mixed with stable isotopes in the same chemical form to the extent that the rate of energy expenditure within this material does not exceed 0.3 rad/week (corresponding to 30 ergs/gm of element per week.)

(d) Disposal in the Ocean

(1) Radioisotopes shall not be disposed of in the ocean unless:

(i) The radioisotopes are encased in a suitable container having "over-all" density of not less than 1.4 times the density of the water.

(ii) The radioisotopes are disposed of in an appropriate ocean

disposal area, at a depth of not less than 100 fathoms, designated by a lawful maritime authority having such jurisdiction.

(2) Item 1(1) above shall not apply to radioisotopes that have been diluted and homogenously mixed with a stable isotope of the same chemical form to the extent that the rate of energy expenditure within this material does not exceed 0.3 rad per week.

30.87 Instructions, Recommendations, and Standards

Each person authorized pursuant to these regulations to possess or use radioisotopes shall observe and abide by such written instructions, recommendations, or standards issued by the Commission for the safe use, handling, or disposal of radioisotopes: PROVIDED, that such instructions, recommendations, or standards shall have been duly published in the Federal Register; or shall have been delivered by mail to said possessor or user of radioisotopes; or shall have been delivered personally to said possessor or user of radioisotopes by an authorized representative of the Commission.

30.88 Guides

Appropriate "Handbooks" containing current recommendations of the National Committee on Radiation Protection may be used as guides in maintaining safe conditions and in complying with the above-mentioned regulations.

DEC 7 1953

William Mitchell, General Counsel,
Washington

J. W. Ould, Jr., Assistant General Counsel,
Oak Ridge Operations

AMENDMENT OF RADIOISOTOPE DISTRIBUTION REGULATIONS TO PROVIDE FOR
GENERAL RADIOLOGICAL HEALTH SAFETY STANDARDS

In Reply
Refer To : NC:OSH

Enclosed are two copies of a memorandum from the Director, Isotopes Division, to the Director, Research Division, Washington, dated November 30, 1953, concerning the publication of general radiological health safety standards in the Federal Register.

We understand the intent of this memorandum is to focus the picture regarding this matter, and to seek a present expression of the policy views of the Division of Research because of some recent statements by advisors and others to the Director, Isotopes Division, expressing objections to the adoption and publication of health safety standards applicable to radioisotope users.

We believe the attached memorandum presents a good case for continuing the heretofore announced policy of publishing such standards, and we concur in the conclusion expressed in paragraph 31.

Although we did discuss this matter with the Division, and reviewed a draft of a proposed memorandum to Dr. Johnson, the memorandum as prepared in final form was not submitted for our concurrence. We point this out merely because of the fairly positive legal conclusions and opinions which are now expressed in the memorandum. While we do not disagree generally with these conclusions and opinions, in some instances, they possibly fail to recognize other authorities, exemptions, or limitations which might be applicable, and which warrant some qualifying expressions.

J. W. Ould, Jr.
J. W. Ould, Jr.

WFF
Enclosure:
Memo, dtd 11-30-53, to Mr. Johnson

OK CC: Paul C. Aebersold, Director, Isotopes Division, ORO



OFFICE ▶	MC	<i>Legal</i>					
SURNAME ▶	Winstone	<i>Winstone</i>				ISOTOPES PROJECT	3
DATE ▶	12/4/53	DEC 7 1953					