

APPLICATION FOR MATERIAL LICENSE

LEL 28282
030-30804

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NM55
WASHINGTON, DC 20556

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCLEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1050 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94506

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER _____
- C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

EISAI RESEARCH INSTITUTE OF BOSTON, INC.
128 SPRING STREET
LEXINGTON, MA. 02173

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

EISAI RESEARCH INSTITUTE OF BOSTON, INC.
128 Spring Street
LEXINGTON, MA. 02173

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. Lynn D. Hawkins, Ph.D., Senior Scientist

TELEPHONE NUMBER

(617) 863-5077

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL See Attachment I
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
See Attachment I

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE
Robert U. Johnson, Kawata

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
See Attachment II

9. FACILITIES AND EQUIPMENT
See Attachment III, IV

10. RADIATION SAFETY PROGRAM
See Attachment V

11. WASTE MANAGEMENT
See Attachment VI

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY 3M AMOUNT ENCLOSED \$ \$700.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, F2 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE 9-1-88

Shuichi Saito

Shuichi Saito

Director of Research Coordination

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS	
< \$250K	\$1M - 3.5M
\$250K - 500K	\$3.5M - 7M
\$500K - 750K	\$7M - 10M
\$750K - 1M	> \$10M

b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial - proprietary - information furnished to the agency in confidence)

YES

NO

FOR NRC USE ONLY

TYPE OF FEE APP FEE LOG Oct. 8th FEE CATEGORY 3M

COMMENTS 8912060137 890114 REG 1 LIC 30 20-28282-01 PDR

APPROVED BY *S. Kimberly*

AMOUNT RECEIVED \$700 CHECK NUMBER 385

DATE 10/7/88

12 SEP 1988

109564

Application for Byproduct Material License to NRC
Eisai Research Institute of Boston, Inc.

Attachment I

Item 5. Radioactive Material

Element and Mass No.	Chemical/Physical Form	Max Activity on Hand	Relative Use
Phosphorus- 32	Organic and Inorganic Liquids non-volatile)	50 mCi	Less often
Iodine-125	Nal and Proteins	50 mCi	Most often
Sulfur- 35	Organic and Inorganic Liquids (non-volatile)	150 mCi	Very rare
Tritium (H-3)	Pharmaceutical Agents	100 mCi	Most often
Carbon- 14	Pharmaceutical Agents	50 mCi	Most often

Item 6. Purpose for which licensed material will be used.

All radionuclides used will be used in microcurie amounts as labelled nucleotides and organic compounds in microbiological and biochemical *in vitro* studies. The I-125 will be used in RIA and receptor binding assays, and in low amounts for labelling molecules. The P-32 will be used occasionally in millicurie amounts for labelling molecules.

Item 7.a.

CURRICULUM VITAE

NAME: Robert U. Johnson

DEPARTMENT: Environmental Health and Safety, University Health Services

TITLE: Director, Radiological Services and Assistant Radiation Safety Officer

DATE/PLACE OF BIRTH: September 26, 1928; Beverly, MA

CITIZENSHIP: United States

HOME ADDRESS: 31 Chipman Road; Beverly, MA

ACADEMIC TRAINING:

<u>Degree</u>	<u>Discipline</u>	<u>Institution</u>	<u>Date</u>
----	Science	Beverly High School	1946
B.S.	Chemistry	Northeastern University	1951

POSITIONS HELD:

Director, Radiological Services & Assistant Rad. Safety Officer	University Health Services Cambridge, MA	1959---
Assistant Radiation Safety Officer	Mass. General Hospital Boston, MA	1963---
Acting Radiation Safety Officer	Mass. General Hospital	1965-1966
Radiation Safety Officer	Boston Bio-Medical Research Inst.	1969---
Radiochemist	U.S.A.E.C. Raw Materials Development Lab (Nat'l Lead Co.) Winchester, MA	1954-1959

MISCELLANEOUS

Laboratory Instructor	New England Roentgen Society	1964---
Consultant	MA Nuclear Incident Advisory Team Cambridge Nuclear Co. Boston University Children's Hospital Med. Center	1963 1961-1971 1971--- 1971---
U.S. Army	Classification & Assignment Sgt. (Korean Veteran)	1951-1954

Item 7.a. (cont.)

Professional Affiliation

Health Physics Society (Nat'l &
Local Chapters)
Boston Medical Physics Society
Conf. on Radiological Health

Member, Radioisotope Committee

Harvard University, Mass. General Hospital, Retina
Foundation, Boston Biomedical Research Institute,
Children's Hospital Medical Center, Peter Bent
Brigham Hospital (ex officio), Beth Israel Hospital

ADDITIONAL POSITIONS:

Radiation Safety Consultant:

- a. Micro-Dynamics Inc. Woburn, MA 01801
- b. Millipore Filter Corp., Bedford, MA 01730
- c. Gamma Diagnostic Laboratories, Attleboro
Falls, 02763
- d. KOR, Cambridge, MA 02140
- e. Nuclear International Co. Waltham, MA
1974-1980 (Business Terminated)
- f. Veterans Administration Hospital, West
Roxbury, MA

Item 7.b.

Curriculum Vitae
Tsutomu Kawata

Education

April 1969 - March 1972
Sapporo Asahigaoka Municipal High School
Hokkaido, Japan

April 1973 - March 1977
Faculty of Pharmaceutical Science
Hokkaido University
Hokkaido, Japan

April 1977 - March 1982
Division of Pharmaceutical Science
Graduate School
Hokkaido University
Hokkaido, Japan
Ph.D. in Pharmaceutical Science

Employment

August 1988 - present
Senior Scientist, Eisai Research Institute of Boston, Inc.
128 Spring Street
Lexington, MA 02173

April 1982 - July 1988
Research Pharmacologist
Tsukuba Research Laboratories
Second Exploratory Drug Research Division
Eisai Co., Ltd.
Ibaraki, Japan

Research Activity

1982 - 1987 Research on anti-diabetic drugs
1987-present Research on PAF antagonist for therapy of disseminated
intravascular coagulation and endotoxic shock.

Special Qualification

July 1977 Qualified Pharmacist (No. 164855) under Japanese law

Item 7.b. (cont.)

Tsutomu Kawata

Radioactive Research Experience

Hokkaido University

5 Years

^3H : Carbohydrates

^{14}C : Carbohydrates,

^{125}I : Insulin

^3H and ^{14}C were used as *in vivo* probes to investigate the carbohydrate metabolism in rats.

^{125}I was used to measure the serum insulin content of rats *in vivo*.

Tsukuba Research Laboratories

6 Years

^3H : Carbohydrates, Pharmaceuticals

^{14}C : Carbohydrates

^{125}I : Insulin, Cyclic- AMP

^3H and ^{14}C were used as *in vivo* probes to investigate the carbohydrate metabolism in rats. ^3H was used to measure binding of pharmaceuticals to biological receptors *in vitro*.

^{125}I was used to measure the insulin and c-AMP content in the plasma of rats *in vivo*.

Professional Societies

1977 - present The Japanese Biochemical Society

1982 - present Japan Diabetic Society

1985 - present Japan Obesity Society

Theses

Ph.D. (1982) "Hormonal regulation of glucose metabolism in tumor-bearing rats"

M.S. (1979) "Influence of tubercle bacillus on adrenergic regulation in rats"

Publications

T. Kawata and K. Itaya: Effect of reserpinization on insulin secretion in the rat. *J. Pharm. Pharmacol.*, **34**; 377-380 (1982).

T. Kawata and K. Itaya: Potentiation of insulin secretory response of rats by BCG injection. *Japan J. Pharmacol.*, **32**, 255-262 (1982).

Item 7.b. (cont.)

Tsutomu Kawata

T. Kawata and K. Itaya: Potentiation of insulin response of rats by cell wall skeleton extracted from BCG cell wall., *Japan J. Pharmacol.*, **32**; 929-931 (1982)

T. Kawata and M. Ui : "Glycogen synthase" "Branching enzyme" In: S. Baba, et al., (ed) : Rinsho Kouso handbook. Kodansha, 239-240, 560-561 (1982)

H. Kawashima, J. Nagaoka, T. Kawata and T. Wakabayashi, "E-0713, a new antidiabetic agent, improves glucose tolerance and increases glucose-stimulated insulin response in diabetic animals." Proceedings of the Second International Symposium on Treatment of Diabetes Mellitus, Nagoya, Excerpta Medica, Amsterdam-New York-Oxford 307-311 (1987)

H. Kawashima, J. Nagaoka, T. Kawata and I. Yamatsu: Improvement of glucose intolerance in diabetic animals by E-0713, a new antidiabetic agent. manuscript submitted

Patents

Carboximide derivative

S. Souda, K. Miyake, T. Wakabayashi, H. Kawashima, K. Usuki, T. Kawata, J. Nagaoka and N. Nagaoka, Jpn. Kokai Tokkyo Koho, JP 60204784 (Cl. C07C401/12) 16 Oct. 1985

Guanidinobenzoate derivative

S. Souda, N. Shimomura, N. Ueda, S. Miyazawa, T. Yamanaka, K. Miyamoto, I. Hishinuma, J. Nagakawa, N. Nagaoka, H. Kawashima, T. Kawata, J. Nagaoka and T. Wakabayashi. Jpn. Kokai Tokkyo Koho, JP 62155253 (Cl. C07C147/437 10 July 1987

Presentations

T. Kawata and K. Itaya "Regulation of glucose metabolism in Freund's complete adjuvant treated rats." The 50th Annual Meeting of the Japanese Biochemical Society (4D-P4), 1978

T. Kawata and K. Itaya and M. Ui "Change of glucose metabolism and the regulation by hormones in tumor bearing rats." The 52nd Annual Meeting of The Japanese Biochemical Society (1E-a4) 1980

T. Kawata and K. Itaya "Effects of glucagon and epinephrine on gluconeogenic activity in the early stage of tumor growth in rats. The 53rd Annual Meeting of The Japanese Biochemical Society (1c-a9) 1981

Item 7.b. (cont.)

Tsutomu Kawata

T. Kawata and K. Itaya "Adrenal cortex hormone-induced accumulation of liver glycogen in the early stage of tumor growth in rats. The 53rd Annual Meeting of The Japanese Biochemical Society (1c-a8) 1981

J. Nagaoka, K. Usuki, N. Nagaoka, T. Kawata, K. Sugiyama and H. "Glucose tolerance improved by carboxylic acid derivative (E-0713)." The 27th Annual Meeting of Japan Diabetic Society (A320) 1983

H. Kawashima, J. Nagaoka, N. Nagaoka, T. Kawata and T. Wakabayashi. "A new antidiabetic agent (E-0713) improves impaired glucose tolerance in diabetic models." Iupar 9th International congress of Pharmacology, London (1886) 1984

T. Kawata, H. Kawashima, J. Nagaoka and T. Wakabayashi "The action of E-0713 on epinephrine-induced hyperglycemia and increase of glucose turnover rate." The 28th Annual Meeting of Japan Diabetic Society (E306) 1985

H. Kawashima, J. Nagaoka, T. Kawata and T. Wakabayashi "E-0713, a new antidiabetic agent, improves glucose intolerance and increases glucose-stimulated insulin response in diabetic models." The Second International Symposium on Treatment of Diabetes Mellitus, Nagoya (P50) 1985

T. Kawata, J. Nagaoka, H. Kawashima and T. Wakabayashi. "Insulin secretory response increased by E-0713 in ob/ob mice." The 29th Annual Meeting of Japan Diabetic Society (C212) 1985

Application for Byproduct Material License to NRC
Eisai Research Institute of Boston, Inc.

Attachment II

Item 8. Training for Individuals Working in or Frequenting Restricted Areas.

The training procedures that are to be used at ERI will be those guidelines set in the RADIATION SAFETY GUIDE provided as Attachment V in this application packet. Specifically, pages 7 through 15 in appendices 1, 2, and 3 of the RADIATION SAFETY GUIDE provides the details of the training of all individuals who work with or frequent the restricted radioactive use area. All personnel at ERI will be required to read and be aware of the radiation safety guidelines established in the RADIATION SAFETY GUIDE.

All investigators requesting the use of radioactive materials must submit the completed Application for use of Radionuclides form exemplified on page 8 of the RADIATION SAFETY GUIDE.

All trained personnel and requesting investigators will be required to take a written examination as part of the training procedure. Sample questions from the Radiation Safety Training exam and the correct answers are provided as Attachment II.a. A grade of 70% is passing. Individuals who fail the exam are given specific instruction in the areas of their deficiencies and re-tested within one week.

A course instruction is to be provided by ERI's consultant Mr. Robert U. Johnson. See Item 7.a. for a detailed curriculum vitae.

Attachment II.a.

Questions from Sample Test

1. Define the following terms:
 - A. Half Value Layer
 - B. Rem
 - C. ALARA
 - D. "Caution" Radioactive Materials Sign
 - E. Γ Factor
2. What are the three basic factors to minimize personal exposure when working with radioactive materials ?
- 3-5. A ^{137}Cs source is determined to be 30 mCi. The Γ is 3.3 R/hr/mc/cm and its half value layer in lead is 0.65 cm.
 3. What is the unshielded dose rate from the 30 mCi source at 40 cm ?
 4. How much lead must be used as shielding to reduce the dose rate to 2 mr/hr at 40 cm ?
 5. Calculate the additional distance necessary to reduce the dose rate to 2 mr/hr rather than using shielding.
6. NRC regulations require wipe tests of sealed sources at six month intervals. The permissible level of contamination on the wipe is $5 \times 10^{-3} \mu\text{Ci}$. A wipe indicates 110 counts per minute at 20 % counting efficiency. Is this within the permissible limit ? If not, what corrective action should be taken ?
7. Define the term half life and give the half life of Cs-137.
8. What document is entitled, "Notices, Instructions and reports to Workers", and what information does this document provide to you ? What NRC form referred to in the document must be situated so that a worker may see it coming to and going from work ?
9. Describe what is meant by natural background.
10. What is the maximum permissible dose that you are allowed to receive quarterly to the whole body and to the extremities ?
11. Describe gamma radiation and some of the important properties of gamma emitters.
12. What is the significance of a once-in-a-lifetime dose of 25 Rem ? What is meant by LD50 and what dose is generally conceded to be LD50 ? What might be done if this dose is exceeded ?
13. Name two incidents which require reporting to the NRC.
14. What is meant by the calibration of a survey meter and what conditions are required for a calibrated meter ?
15. What is the maximum permissible dose allowed for an unrestricted area and what must be done if this condition is exceeded ?

Application for Self-Contained Dry Source Irradiator License to NRC
ImmuLogic Pharmaceutical Corporation

Attachment II.a. (cont.)

Questions from Sample Test (cont.)

Answers

- 1-A. The thickness of lead necessary to reduce the dose rate by a factor of two.
- 1-B. Abbreviation for Roentgen Equivalent Man
Absorbed Dose (Rads) x Quality Factor = Dose Equivalent (Rem)
- 1-C. As Low As Reasonably Achievable. Term coined by the NRC, the basic factor for maintaining low exposures and releases, and by which any dose exceeding 10% of the permissible dose requires an investigation.
- 1-D. Required to be posted in rooms or areas in which radioactive materials are used or stored in an amount exceeding the quantities expressed in 10-CFR-20, Appendix "C".
- 1-E. The basic factor for calculation of gamma dosage in R/hr/mCi/cm. Calculated from the energies of the gamma rays of the particular radionuclide and the disintegration scheme.
2. Time, distance, and shielding.
3. 61.9 mr/hr.
4. 4.947 HVL or 3.216 cm.
5. 222.5 cm.
6. $110 \text{ c/m @ } 20\% \text{ efficiency} = 550 \text{ d/m} = 0.000248 \text{ } \mu\text{Ci}$, which is less than 5% of permissible.
7. The half life of any radionuclide is the time which it takes to decay to one half of its original radioactive amount. The half life of Cs-137 is ca. 30 years.
8. Instructions to Workers may be found in 10-CFR-19.12 and provides information regarding the requirement for training, following the regulations of the Nuclear Regulatory Commission, and reporting of any incidents or unusual procedures. It also covers the rights of the worker to know any exposure or bio-assay results. NRC #3, which contains information of the responsibilities of the licensee and user and the right to report any uncorrected violations to the NRC. The telephone number of each regional office is contained on this document.
9. Natural background is radiation constantly present in the environment as the result of cosmic radiation, naturally occurring activity in the body and in inanimate materials.
10. The maximum permissible whole body dose is 1.25 Rem/quarter year and 18.75 Rem/quarter year to the extremities.
11. Gamma rays are electromagnetic radiations emitted by the radioactive nuclei as packets of energy, called photons. They are of extremely short wave length and high frequencies. Gammas require metallic (Pb) lead shielding, and dosage is minimized by inverse square law.

Attachment II.a. (cont.)

Answers (cont.)

12. This is a rarely used regulation that enables a worker to receive up to 25 Rem in the event of a life-saving emergency. LD50 signifies that 50% of the personnel receiving such a dose would die. The dose generally conceded to be at LD50 is 650 Rem to the whole body. If one received such a dose, a bone marrow transplant would possibly enable the recipient to recover.
13. Any loss of radioactive material or exposures exceeding the permissible levels must be reported to the Nuc. Reg. Commission. Also, any release of radioactivity in excess of permissible limits and any damage to property.
14. A survey meter must be "calibrated" so that any measured dose rates is a true indication of the dose rate. This calibration must be performed on a scheduled basis with records maintained of the calibration. Any deviation from the true dose rate must be noted on a calibration chart or graph attached to the instrument. The calibration is carried out on two points on each scale separated by at least 50% of the scale. It must be also calibrated after each repair before being used.
15. The maximum dose rate allowed in an unrestricted area is 2 mr/hr at any time during use and less than 100 mr total in 7 consecutive days. However, shielding would be used whenever possible to reduce the dose rate to a minimum level in accordance with ALARA.

Application for Byproduct Material License to NRC
Eisai Research Institute of Boston, Inc.

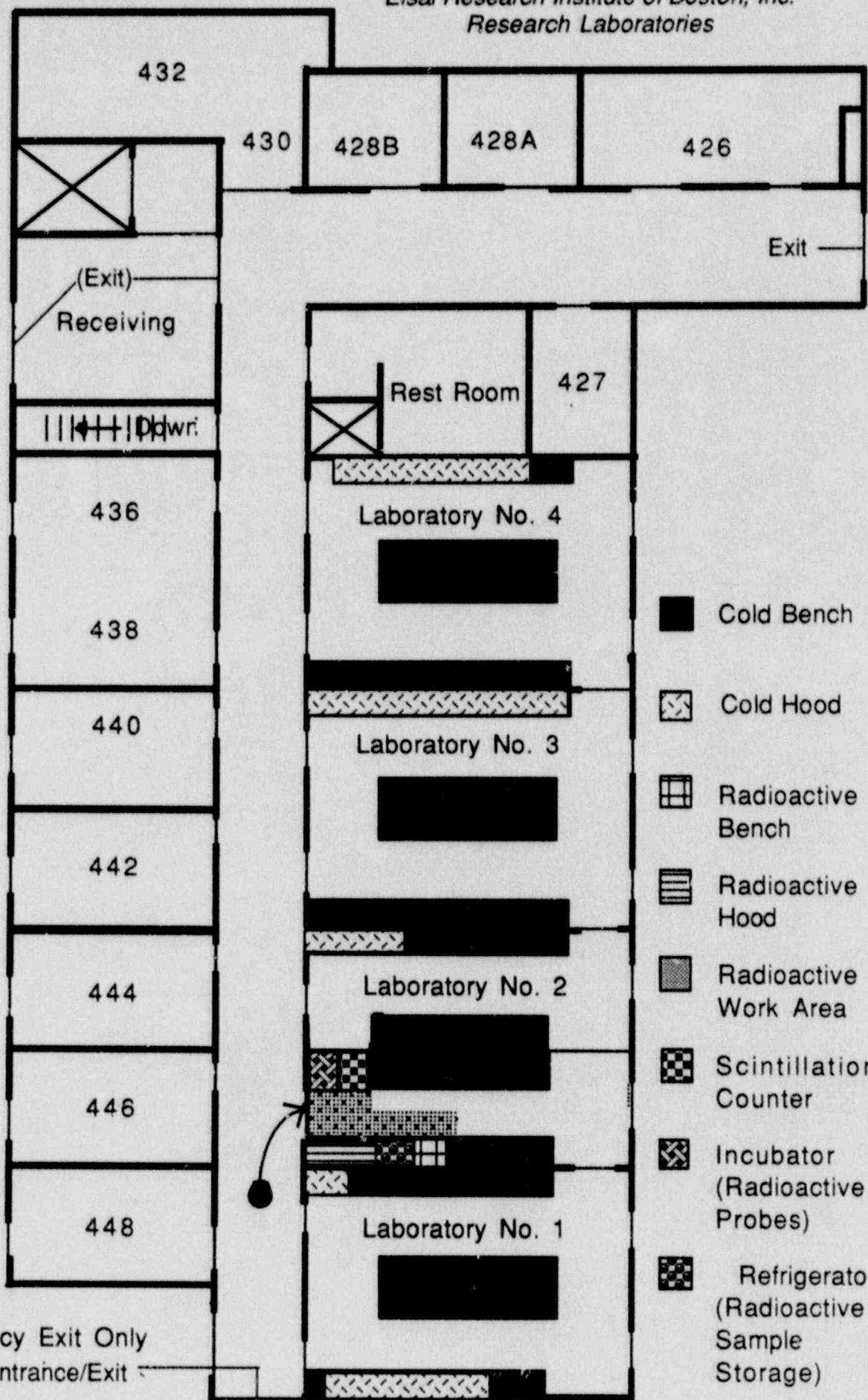
Attachment III

Item 9. Facilities

Floor plans of the ERI facilities on the second floor at 128 Spring Street, Lexington, MA are attached. The laboratory areas in which radioisotopes will be used are indicated.

Features

1. Floor covering: Sealed tile or equivalent.
2. Working surfaces: Formica, epoxy coated stone or equivalent;
absorbent, plastic-backed paper will be used at all
times.
3. Hoods: Impervious surfaces; with minimum of 100 linear feet
per minute air flow across the front of the hood
opening with the windows at normal height.
4. Iodination
Facilities Iodinations will be done in a hood or mini-hood
equipped with an adequate activated charcoal filter
in the exhaust system.
5. Security The entire company facility is separately secured on
a 24 hour basis. Access during business hours is
monitored by administrative staff. Evening access is
controlled by key issued to certain company
personnel. The lab areas are segregated from the
office areas and only authorized personnel are
allowed into the labs. Lab doors are locked at night
and at other times if no one is present in the labs. An
alarm system is armed when no employee is in the
facility.



● Emergency Exit Only
Entrance/Exit

- Cold Bench
- ☒ Cold Hood
- ☒ Radioactive Bench
- ☒ Radioactive Hood
- ☒ Radioactive Work Area
- ☒ Scintillation Counter
- ☒ Incubator (Radioactive Probes)
- ☒ Refrigerator (Radioactive Sample Storage)

Application for Byproduct Material License to NRC
Eisai Research Institute of Boston, Inc.

Attachment IV

Item 9. Radiation Detection Equipment and Calibration

Radiation Detection Equipment

1. Geiger-Mueller Survey Instrument.

Model: Ludlum Model 3 or equivalent.

Use: Monitoring the use of I-125 and P-32.

Range: 0.025 to 200 mr/hr.

Calibration: to Ra-226. See following page for procedure.

Check: Check source.

2. Liquid Scintillation Counting Spectrometer

Model: Beckman LS5000 TA.

Use: Experimental analysis and analysis of contamination smears.

Range: 30 cpm/sample to 10,000,000 cpm/sample.
For tritium 50 dpm/sample detectable limit.
For C-14, I-125, P-32, 100 dpm/sample detectable limit.

Calibration: As required, by use of standard radionuclide sources, e.g., NEN cat. no. NES-202 or NES-203.

Check: At least weekly, with one or more of the standard sources named above.

Application for Byproduct Material License to NRC
Eisai Research Institute of Boston, Inc.

Attachment IV(cont.).

Item 9.

Calibration Procedure

Geiger-Mueller Survey Meter

Vendor: Mr. Robert Johnson
Independent Consultant (and Harvard University Radiation Safety
Officer)
Approved through Harvard University Broad License
(C.V. enclosed at the end of this attachment.)

The survey instruments are calibrated routinely every six months using 50 mCi, 5 mCi, and .05 mCi Ra-226 gamma 'instrument calibration' sources. The exposure rate has been determined by the vendor, using ionization chambers whose calibration is traceable to the National Bureau of Standards. The typical procedure is as follows:

1. The instrument is placed in a free air uniform gamma field of the calibrator where the exposure rate corresponds to the mid-scale reading of the meter on a given range setting, and calibrated at the midpoint. The exposure rate is determined by a Victoreen R-chamber of an appropriate range.
2. The instrument is then placed in the gamma field at exposure rates corresponding to one third of the full scale and two thirds of the full scale reading. If the meter readings at either of these two points differ from the true exposure rate by more than 10%, the meter is adjusted by repeating steps 1. and 2. until the meter is within 10%.
3. Steps 1. and 2. are performed for all range settings of the instrument which can be calibrated with this source.
4. A calibration label is affixed to the instrument, specifying the ranges that have been calibrated and the date of calibration.
5. A certificate of calibration (sample sheet on following page) is provided for each instrument calibrated. Calibration certificates are kept at the company for a minimum of two years.

Application for Byproduct Material License to NRC
Eisai Research Institute of Boston, Inc.

Attachment V

EISAI RESEARCH INSTITUTE OF BOSTON, INC.

RADIATION SAFETY GUIDE

AUGUST 15, 1988

Approved:

Tsutomu Kawata

Tsutomu Kawata, Ph. D.
Radiation Safety Officer

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INTRODUCTION

All uses of radioactive material at ERIBI are controlled by the radiation protection program.

**NO WORK WITH SOURCES OF IONIZING RADIATION CAN
BE INITIATED UNLESS AUTHORIZATION HAS BEEN
OBTAINED FROM THE RADIATION SAFETY OFFICER.**

All uses of ionizing radiation (except ultra-violet radiation) in Massachusetts are controlled and regulated by the U.S. Nuclear Regulatory Commission (NRC). ERIBI has received a license from the NRC to use limited amounts of radioactive material in biological research. We have established a radiation safety program to give the necessary assurances to the NRC as well as the company management that all potentially hazardous sources of radiation will be used safely.

This guide describes the organization of the program and specifies the regulations, policies and procedures and practices which are to be followed in using radiation sources at ERIBI. The guide was presented to the NRC as describing the ERIBI radiation safety program. It was accepted as such and so referenced in the license subsequently issued. Consequently, the guide is a legal document governing all uses of radiation at ERIBI.

It is ERIBI's policy to encourage the use of radiation where appropriate, but always with the insistence that there be no unwarranted radiation exposure; thus, due regard must always be given to the safety and welfare of the radiation workers and the general population as well as to the protection of ERIBI property and liability. The ERIBI operational policy places ultimate responsibility on the person who is supervising the use of radiation sources. These supervisors can satisfy their responsibilities by adhering to this guide and by requesting assistance from the Radiation Safety Officer (RSO) when there are questions or suspected problems.

This guide is organized in the following manner:

- Section 1 - General description of the ERIBI Radiation Safety Program, Organization and Responsibilities
- Section 2 - Detailed Procedures and Practices

1. Description of the ERIBI Radiation Safety Program

There are three levels of authority in the radiation safety program:

The Radiation Safety Officer (RSO)

The RSO together with the management of ERIBI establishes the radiation safety policy such that:

1. Unwarranted radiation safety exposures of ERIBI employees and general public are avoided.
2. Compliance with all the federal and state regulations is assured.
3. ERIBI property and liability are protected.

Specifically, the RSO meets these responsibilities by routinely monitoring all uses of radioactive material to ensure that: (a) each use is by or under the supervision of a properly authorized supervisor, (b) that the appropriate personnel and environmental monitoring equipment is being used and (c) that radioactive material is properly secured against unauthorized removal when not in use.

The Supervisor

The supervisor is a person permitted by the RSO and NRC to use radiation sources. (S)he has primary responsibility for the radiation safety associated with each source under his/her control. He must ascertain that each person under his supervision using these sources is properly trained and aware of the attendant hazards (see Training Requirements). He must also assure that use of the sources conform to all the safety conditions of this authorization and those of this guide.

The Supervised User

These individuals must use the sources of radiation only under the direction of a supervisor. They must follow those procedures and practices established by the supervisor. All users are required to attend a Radiation Safety Training Program before they begin work (see Training Requirements).

2. Radiation Regulations, Policies, Procedures and Practices

a. Federal Regulations

The Nuclear Regulatory Commission has established "Standards for Radiation Protection" 10CFR20 (see Appendix for a copy). These standards must be strictly adhered to during all uses of by-product material. The NRC also has adopted regulations which assure that workers will be advised of the sources of radiation being used, the hazards, the safety precautions in effect, etc. at the place of employment. These rights are present in "Notice of Instructions and Reports to Workers; Inspections" 10CFR19 (see Appendix for a copy).

b. ERIBI Policies and Procedures

The management of ERIBI recognizes both the NRC regulations and company policy of preventing unnecessary exposures to radiation as the basic criteria for establishing the radiation safety policies and procedures. The principle means by which the company assures the safe use of sources of radiation are:

1. To require that a person be authorized to use or supervise the use of radiation sources.
2. To require that the acquisition of radiation sources be approved by the RSO and that all receipts and transfers, including disposal of radioisotopes, be channeled through the RSO.

Specific procedures and practices have been established for most routine or recurrent situations to assure compliance to the regulations and company policy. For unusual situations, the RSO will interpret the existing regulations, policies and procedures to establish guidelines.

These are the established procedures and practices:

1. Authorization to Use Radioisotopes (Appendix 1)
2. Training of Workers (Appendix 2)
3. Use of Radioisotopes (Appendix 3)

c. Professional Standards

The RSO also uses as operational guides the published data and recommendations of professionally recognized national and international committees and organizations concerned with health physics or radiation protection, examples of which are:

1. National Council on Radiation Protection (NCRP)
2. International Committee on Radiation Protection (ICRP)
3. International Atomic Energy Agency (IAEA)
4. Health Physics Society (HPS)

APPENDIX 1

Authorization to Use Sources of Radiation

An individual can use or possess a source of radiation only after (s)he is authorized. To be authorized, an individual must be able to present evidence of proper training and experience. An application must be submitted to the RSO and the RSO must approve the application and forward it to the NRC. A formal written authorization must be obtained from the RSO before work can begin.

The authorization will be reviewed and updated when the company NRC license is submitted for renewal. If an authorized supervisor wishes to use sources of radiation different from those for which his group has been authorized, if he wishes to increase the possession limits or change the experimental conditions, he must receive an amendment to his authorization before the change can be put into effect. The RSO will evaluate requests for amendment and, as necessary, inform and request approval from the NRC for amendments to the company license.

A copy of the application for authorization to use radionuclides is on the next page.

EISAI RESEARCH INSTITUTE OF BOSTON

APPLICATION FOR USE OF RADIONUCLIDES

Instructions. Complete application and submit to Radiation Safety Officer. Authorization for use requires signed approval of Radiation Safety Officer.

Name of Applicant **Social Security Number of Applicant**

Department & Supervisor **Location where Isotopes will be used / stored**

Radioactive material(s):

List chemical symbol and mass number of each Form of Material (Chemical and/or Physical) Possession Limit (mCi)

Training and Education

Subject Covered	Course		On-Job Training		Institution	Date Completed
	Yes	No	Yes	No		
A. Principles and Practices of Radiation Protection:						
B. Measurements and Monitoring Techniques						
C. Mathematical principles for Calculating Activity						
D. Biological Effects of Radiation						

Experience (actual use of radioactive materials)

Isotope Maximum Activity Where Used Duration of Use Type of Use

I have read, understand, and agree to abide by ERIBI's Radiation Safety Protection program.

Applicant Signature _____ Date: _____

RSO Signature (Approval): _____ Date: _____

APPENDIX 2**TRAINING OF WORKERS**

Individuals using radioisotopes under an NRC license have certain rights as prescribed in 10CFR19 "Notices, Instructions and Reports to Workers; Inspections" (see Appendix 4). In accordance with Part 19, a copy of the ERIBI license and a copy of the Notice posted in radioisotope areas to advise persons in those areas where work is being done and to describe the documents and regulations pertinent to that work are included in this Appendix.

ERIBI has designed its training program to assure that all persons working in or frequenting areas of radioisotope usage are aware of the attendant hazards. All persons using radioisotopes or frequenting areas where radioisotopes are used must attend a Radiation Safety Training Program consisting of material as shown in the outline appearing in this appendix. The RSO shall keep records of attendance at these orientations.

The training program consists of 8 hours of instruction and a written examination. There will be two portions to the training program: 1. A portion targeted for all prospective users of radioisotopes within the company dealing with both the scientific background of radiation and safe procedures for personal use and 2. A portion targeted for ancillary personnel (custodial, security, maintenance, etc.) describing the practical aspects of working in a radiation area -- understanding signage, basic work and emergency procedures, and commonly used equipment and areas, etc.

The RSO shall determine at the time of application for authorization amendment or renewal if the training and experience of the user is adequate or if additional training or experience is required. All company personnel handling radioisotopes will attend both portions of the radiation orientation and must take and pass the exam. Ancillary personnel will attend the second portion of the orientation lecture when beginning work with the company and annually thereafter.

Radiation Safety Training Program Outline

1. Why are we here?
 - a. Regulations
 - b. Orientation to ERIBI Radiation Safety Program
2. All uses of radiation require a license
3. Description of ERIBI licenses
4. Licenses require ERIBI to assure safe use through:
 - a. Organization
 - b. Facilities and Equipment
 - c. Evaluation
 - d. Control
 - e. Services
5. Radioactivity and radioactive decay
6. Interaction of radiation with matter
7. Dosimetry (Roentgen, the Rad, the Rem)
8. Bioeffects:
 - a. Somatic
 - b. Genetic
9. Regulations - based on ICRP and NCRP recommendations
 - a. 10CFR20
 - b. 10CFR19
 - c. Radiation Protection Guides
 - 8.10 As low as reasonably achievable
 - 8.13 Pregnant Women
 - d. Posting
 - e. Privacy Act; NRC Forms 4 and 5

Radiation Safety Training Program Outline (Con'd)

10. ERIBI Radiation Safety Program
 - a. Management Responsibility
 - b. Radiation Safety Officer
 - c. Evaluation
 - d. Compliance
 - e. Services

11. Laboratory Practices
 - a. External hazards, including X-rays
 - b. Internal hazards
 - c. Surveys
 - d. Instrumentation-which do you use?
 - e. Records
 - f. Waste disposal
 - g. Labelling and marking
 - h. Storage
 - i. Restriction of access
 - j. ALARA-As low as reasonably achievable
 - k. Emergency Procedures (posted)

12. Specific Isotope Usage and Procedures
 - a. Tritium (H-3)
 - b. Carbon 14
 - c. Phosphorous 32
 - d. Iodine 125
 - e. Chromium 51
 - f. Concept of MPC and regulatory requirements
 - g. Radiation Exposure Artifacts
 - h. Care of Personnel badges
 - i. Ordering radioisotopes
 - j. Marking of waste containers
 - k. Changes in experimental procedure
 - l. Hesitancy to ask for help; where to get help
 - m. Rules for use of radioisotopes

CAUTION

Work with sources of radiation is being carried out in this area.

In accordance with the United States Nuclear Regulatory Commission Regulation 10CFR19.11, the following documents relating to the work are available to you from the Radiation Safety Officer.

1. 10CFR20 - which describes the Nuclear Regulatory Commission Standards for Radiation Protection which must be adhered to in the use of sources of radiation.
2. 10CFR19 - which describes the Nuclear Regulatory Commissions Regulations pertaining to notices, instructions, and reports to workers and inspections of radiation activities.
3. Regulatory License and Applications - which specify the special conditions under which radiation work must be carried out.
4. ERIBI Radiation Safety Guide - which specifies ERIBI radiation safety policies and procedures.
5. ERIBI Authorization - under which the work in this area is being carried on.

Maintenance Staff

Procedures for Handling Equipment in Labs Using Radioactive Materials

1. Any device which has a radiation symbol on it (except X-ray producing machines) might be contaminated with radioactive material. Before you work on or around such a device, contact the Radiation Safety Officer (RSO) so that the device may be checked for safety.
2. Equipment within or servicing a radioisotope laboratory which may be contaminated by radioactive material includes hoods, exhaust blower motors, pumps, drain pipes, ventilation ducts, etc. Call the RSO to check before beginning work on any such equipment.
3. If you think you may have gotten some radioactive material on your skin or clothing, wash it off as soon as possible, and then call the RSO so that he can assure you that all the contamination has been removed. Do not leave the general area until you have been checked. Do not panic! The risk is quite low.
4. If you have questions, call the RSO.

Custodial Staff Instructions

What to do About Radioactive Materials

1. Rooms which have the radiation symbol shown on doors or on equipment may contain radioactive materials. You should be careful when working in these rooms. You can sweep, mop, and wax the floors and remove the waste which is not labelled with the radiation symbol, just as in any other room.
2. Any container (box, bottle, carton, etc.) which has radioactive material in it will have the radiation symbol on it. You should not touch these containers. If the contents of these containers are spilled, **DO NOT TOUCH THEM OR ATTEMPT TO CLEAN THEM UP.** Tell your supervisor or the Radiation Safety Officer (RSO).
3. **DO NOT** empty any waste container which has the radiation symbol on it.
4. **DO NOT** empty any waste container which has waste material, such as boxes or bottles, with the radiation symbol in it. Tell your supervisor about it.
5. **DO NOT** eat, drink, smoke or apply cosmetics in any lab or in any room which has the radiation symbol on its door.
6. In an emergency, or if you have any questions, ask your supervisor or the RSO for help.

APPENDIX 3

USE OF RADIOISOTOPES

The authorized supervisor is responsible for seeing that the users of radioisotopes under his authorization comply with all the governmental regulations, the specific conditions and limitations of his authorization, and the procedures and practices outlined in this appendix. He ascertains that all persons who use radioisotopes under the coverage of his authorization are supervised, properly trained and experienced, aware of the attendant hazards, and observe the procedures of this guide.

Training and Experience

See Appendix 2 of this guide.

Receipt, Transfer and Disposal of Radioactive Material

The RSO must approve all intended receipts and subsequent transfers of radioisotopes. All radioisotopes must be shipped to this address:

Eisai Research Institute of Boston
128 Spring Street
Lexington, MA 02173 CHECK THIS *****
Attn: Radiation Safety Officer

A purchase order must be used to order radioisotopes. It must be signed by the RSO before distribution. The NRC license number and Authorized Supervisor's name must be typed on the purchase requisition beneath a description of the radioisotope ordered. A purchase requisition cannot be used to confirm a radioisotope order unless the authorized user obtains prior verbal approval from the RSO. Radioisotopes cannot be ordered on a blanket order without approval from the RSO.

All radioisotopes are checked for contamination and their receipt is recorded for legal purposes by the RSO or his designate. The radioisotope is then delivered to the authorized supervisor. See Appendix 4 for procedures and forms.

If an authorized supervisor wants to: (a) move the radioisotope to a location other than those specified on his authorization, or (b) transfer an isotope to another authorized person, he must first obtain approval from the RSO.

Receipt, Transfer and Disposal of Radioactive Material (Con'd.)

All radioactive material must be disposed of through procedures approved by the RSO. Only those small amounts of liquid radioactive waste allowed by law may be disposed of down the drain of designated sinks. Liquid waste must be placed in a properly labelled plastic container. Solid waste must be placed in a properly labelled container lined with a plastic bag. Liquid scintillation vials should be kept separate. All radioactive waste will be packaged according to the waste vendor's specifications for removal to the disposal site.

Radiation Surveys

The RSO conducts routine radiation and contamination surveys of all laboratories. The user must supplement these routine surveys as follows:

RADIATION SURVEYS ARE TO BE MADE BY THE USER
AFTER EACH EXPERIMENTAL RUN OR AT THE END OF
DAY RADIOISOTOPES ARE USED IN ORDER TO DETERMINE
THE EXTENT OF RADIOACTIVE CONTAMINATION AND TO
ASCERTAIN THAT ALL WASTE AND STOCK MATERIAL
HAS BEEN STORED OR PROPERLY DISPOSED OF.

The RSO survey is conducted biweekly when millicurie amounts of radiation are in use and monthly whenever microcurie amounts are used. All labs are surveyed with an appropriate calibrated survey meter. Wipe tests are taken on all bench tops, hood ledges, sink areas, storage and waste disposal areas. Surveys will also check for proper labelling, signage, and adherence to rules and regulations by users.

When material is known to have been spilled or become airborne, wipe test surveys of the affected area should be made. Such tests can be made with filter paper or squares of any absorbent paper, and the wipes counted with an appropriate counting instrument. The RSO should be called if a researcher has reason to believe his work has resulted in gross contamination or constitutes an emergency situation. (See Emergency Procedures below.)

No levels of removable contamination are acceptable. Users with contaminated work areas will be given 24 hours to decontaminate their area after which a follow-up survey will be made. Fixed contamination (if and when discovered) will be shielded to background for the duration of isotope activity.

All radiation survey reports will be maintained by the RSO for inspection by the NRC.

Storage of Radioisotopes

Radioisotopes must be stored to permit access only to the authoree and those whom he designates. Each area and room where radioisotopes are stored must be posted with a radioactive material sign. Radiation levels around storage areas should be measured. If radiation doses could exceed five (5) millirem per hour in an occupiable area, the area must be posted with a radiation area sign. Proper signs can be obtained from the RSO.

ERIBI 'decay-stores' waste from P-32 (half life 14 days) and Cr-51 (half life 27.8 days). Paper, plastic, and other lab trash expendibles are securely stored in covered containers by isotope in a separate, lockable storage room for 10 half lives. The waste is monitored with a survey meter and discarded in the trash only when no radiation above background is detectable.

See Appendix 4 for Radioisotope Inventory Form.

Records

Each user should maintain a radioisotope log to record the receipt use and disposal of all radioisotope he(sha) receives. This is a government regulation. The log should also be used to record the date and results of radiation and contamination surveys, even when the results are negative. This log is subject to inspection by the NRC. See Appendix 4 for examples of these logs.

Other records required by federal law are kept by the RSO.

Restriction of Radioisotopes Areas

Access to areas where radioisotopes are stored and used must be restricted to those persons cognizant of the associated hazards. This is a government regulation.

Radioactive Waste

Radioactive waste must be disposed of through procedures appoved by the RSO. No waste is to be washed down drains, incinerated, or otherwise disposed without prior cleararice from the RSO. A copy of the detailed procedures for waste disposal is given in Appendix 4.

Movement of Radioisotopes

Radioisotopes are not to be moved from authorized places of storage and used without the prior approval of the RSO.

Emergency Procedures

A radiation emergency occurs when a set of circumstances results in hazardous radiation levels, hazardous concentrations of airborne radioisotopes, or gross contamination of property. Examples of radiation emergencies and actions to be taken are:

- a. Personnel Contamination
 - 1) Remove contaminated clothing.
 - 2) Wash contaminated skin with mild soap and water. Do not use abrasives.
 - 3) Call the RSO. After hours, refer to the emergency call list.
- b. Spill of radioisotope where radioisotope does not become airborne
 - 1) Wipe up with absorbent paper using a blotting motion so you do not spread contamination.
 - 2) Dispose of contaminated paper in radioactive waste container.
 - 3) Call the RSO. After hours, refer to the emergency call list.
- c. Volatilization of liquid or dispersal of solid radioisotope outside a ventilated enclosure
 - 1) If possible, keep contamination localized by closing doors and restricting access to area.
 - 2) Leave the area.
 - 3) Call the RSO. After hours, refer to the emergency call list.
- d. Fire in radioisotope area.
 - 1) Treat fire in normal manner.
 - 2) Call the RSO. After hours, refer to the emergency call list.

ALWAYS USE COMMON SENSE IN HANDLING RADIATION EMERGENCIES, AND CALL THE RSO AS SOON AS PRACTICAL. DO NOT TRACK OR OTHERWISE PERMIT RADIOISOTOPES TO BE SPREAD INTO CLEAN AREAS.

ERIBI RADIATION SAFETY OFFICER: _____

DAYTIME PHONE: _____

WEEKEND AND EVENINGS: Refer to the emergency call list.

A more detailed procedure can be found below.

Personnel Monitoring

The RSO determines the need for personnel dosimetry during the authorization evaluation or evaluation of amendment requests.

ERIBI requires all personnel using or routinely exposed to radioisotopes to wear film badges. Badges are supplied and analyzed monthly by R. S. Landauer, Jr. & Co., 39 Milltown Road, East Brunswick, NJ, 08816. Monitoring reports are returned to the RSO, who reviews them alone with an independent radiation safety consultant to assure that exposures are maintained within acceptable levels.

The authorized supervisor has the responsibility to assure that all persons who use radioisotopes or work in his(her) area wear appropriate radiation dosimeters when required.

Radioisotope Laboratory Design

The design and furnishings of a laboratory must be commensurate with the hazards presented by the radioisotope and its condition of use. Each laboratory must, therefore, be evaluated individually by the RSO in light of its intended use. In practical terms, some possible requirements are that:

- a. Bench tops or other surfaces on which radioisotopes will be used must be stainless steel or covered with a permanently impervious surface.
- b. Floors must be covered with an impervious material; properly waxed, vinyl asbestos tiles are normally acceptable.
- c. Walls must have a smooth, crack-and hole-free surface.
- d. Proper room ventilation and adequate radioisotope storage must be provided.

Rules for Working with Radioactive Materials

A set of laboratory rules found to be very useful in reminding laboratory workers of good radiation safety practices is found below. Copies of these pages should be posted in each laboratory by the RSO. Each authorized supervisor should assure that these instructions are kept prominently displayed in work areas.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

ROUTINE PROCEDURES

<i>Eating, drinking, smoking</i>	Eating, drinking, smoking or using cosmetics is not permitted in this laboratory.
<i>Wash hands</i>	Wash hands after handling any radioactive material before going about other work. Always wash before handling objects which go into the mouth, nose, or eyes. Keep fingernails short and clean.
<i>Pipetting</i>	<u>Never</u> pipette anything, even water, by mouth.
<i>Protective Clothing</i>	Always use rubber or plastic gloves when handling radioisotopes. Lab coats should be worn in the lab and left in the laboratory.
<i>Confine the Activity</i>	Always work over trays lined with absorbent material. Keep and transport radioactive materials doubly contained.
<i>Spills</i>	Notify the Radiation Safety Officer <u>of all spills</u> except those of a very minor nature.
<i>Labelling</i>	Label radioactive material with your name, date, isotope and quantity of isotope.
<i>Before Leaving</i>	Before leaving the laboratory, clean up and monitor your work area and yourself.
<i>Disposal of Liquid radioactive waste</i>	Liquid radioactive materials should be disposed of through the Radiation Safety Officer. They should be held in plastic containers or in metal containers if the material is incompatible with plastic. The quantity of isotope, the isotope name, date, and the user's name should be recorded in a log kept with the container. <u>No radioactive material should be disposed of via the sink without approval from the RSO or group supervisor.</u>

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

ROUTINE PROCEDURES (Con'd.)

- Disposal of **Solid*** Solid radioactive waste should be placed in plastic-lined boxes or containers. The quantity being disposed of, date, user and the isotope should be recorded in the waste log kept with the container.
- Counting Room* Take only prepared samples into the counting room. No potentially contaminated material or apparatus is permitted in the counting room. This includes lab coats.
- Hoods* Materials which could become airborne must be stored and used in a hood. Hood ventilation should be left "ON" at all times.
- Food* Never keep or store beverages or food in radioisotope labs, in refrigerators or freezers with radioisotopes.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

EMERGENCY PROCEDURES

Be prepared for an emergency by mentally rehearsing the following:

EXTREME HAZARDS

Hazards such as high radiation levels or the possibility of airborne contamination from dry or volatile radioactive materials.

Evacuate Evacuate the laboratory immediately; close the door and lock it.

Call RSO Call the RSO immediately. If you have to leave the area to do so, remove your shoes if you suspect contamination and do not touch anything unnecessarily.

OTHER HAZARDS

Hazards such as spills or suspected spills of radioactive material where the material does not become airborne.

Keep Calm Keep calm, use common sense, protect people, do not spread contamination (always assume you are contaminated until a survey proves otherwise).

Confine Contamination Localize the spill. Right tipped container; drop absorbent material on the spill. Damp down a dry spill.

Do not track contamination about the laboratory. Call, do not go for help, if possible!

Close door, and where possible adjust the ventilation to prevent spread of airborne material.

Check shoes before leaving the area of a cleaned up spill.

RULES FOR WORKING WITH RADIOACTIVE MATERIALS

EMERGENCY PROCEDURES (Con'd.)

Protect Personnel

Remove contaminated clothing and wash contaminated parts of the body with detergent.

Be especially thorough in flushing out wounds.

Warn other workers.

Decontaminate

If thorough washing with detergent does not remove contamination from body, consult the RSO.

You will be expected to perform the major work of decontamination of the area of your spill. The RSO will survey for contamination and advise on procedures and assist as necessary.

All suspected contaminated persons and areas must be monitored after decontamination and before work is resumed.

IN ALL EMERGENCIES, EXCEPT VERY MINOR SPILLS OF RADIOACTIVE MATERIALS, THE RSO SHOULD BE CALLED AS SOON AS POSSIBLE.

DO NOT TRACK OR OTHERWISE PERMIT RADIOISOTOPES TO BE SPREAD INTO CLEAN AREAS.

APPENDIX 4

SPECIAL PROCEDURES

Laboratory Survey Procedure

1. Laboratory contamination surveys should be done on a routine periodic basis with the period determined by the level of activity. They should be done often enough so that the possibility of contamination is minimized.

Surveys should be done by anyone using radioactive material immediately after the completion of an experimental procedure.

2. A survey data notebook should be kept, containing layouts of the laboratories indicating the points at which the wipes were made and data tables containing the results of the counting of the wipes.
3. Wipes are made using filter paper moistened with water or if necessary, another solvent for the material in use. Approximately 100 square centimeters of surface should be wiped.
4. Penetrating radiation, e.g. P-32, I-125, can be monitored with the G-M survey instrument.

EISAI RESEARCH INSTITUTE OF BOSTON**LABORATORY SURVEY RECORD**

Room: _____ Supervisor: _____

Radionuclides Used: _____

See room plan on reverse side for key to locations.

<u>Survey Date</u>	<u>Surveyer</u>	<u>Contamination</u>		<u>Radiation Field</u>		
		Location	cpm/wipe	dpm/wipe	Location	mR/hr.

Instructions

1. On the reverse side sketch a plan of the lab indicating by number the locations at which the wipes are taken.
2. Contamination surveys shall be done using absorbent filter paper (moistened with an appropriate solvent if necessary). Wipe approximately 100 cm² of surface area. Count the wipes in the LSC (open channel). Record the instrument efficiency here: _____ %. Divide the cpm's recorded by the efficiency to calculate the dpm's. Record these amounts above next to the cpm's. An Activity of 200 dpm/wipe or greater indicates significant contamination. Contaminated areas must be cleaned immediately and the area resurveyed.
3. Radiation surveys (if necessary) should be performed with a properly operating, calibrated G. M. survey instrument. An exposure rate in excess of 0.1 mR/hr in areas frequently occupied by humans should be shielded.

Radioactive Material Receipt and Opening Procedure

Package Receipt

1. Do not accept a radioisotope shipment that is damaged.
2. A contamination survey must be made within three (3) hours after receipt of a radioactive material shipment (within 18 hours if the delivery is after hours).
3. Radioactive material shipments should be separated from the non-radioactive shipments upon receipt. The Radiation Safety Officer should be notified immediately.
4. The date and time of the receipt should be recorded on the delivery form.

Package Opening

1. Wear gloves and protective clothing when opening the package.
2. Wipe the outside shipping container surface and count the wipes to check for contamination (see note below). Record the results.
3. Using the G. M. survey meter, measure the radiation levels at the surface of the container and if necessary at one meter from the surface. Record the results.
4. Open the package, and take wipe of the successive layers of containment, down to the vial containing the radioisotope (or the outside of the package if it is sterile wrapped). Count these and record the results. If there are no counts above background, container may be discarded in regular trash; otherwise container must be discarded with solid radiation waste.
5. Record any signs of damage to the package or to the vial.
6. If there is contamination or an excessive radiation level check the NRC regulations (10CFR20.205) to see if the NRC or the shipper must be notified.
7. The wipes should be counted in the Liquid Scintillation counter.

Delivery of Radioisotope to User

Do not leave the package unattended; deliver it immediately to the user so that it may be stored correctly. If the user cannot be found, contact the supervisor of the lab where delivered was to be made for proper disposition.

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Radioisotope Receipt and Delivery

Radioactive Material _____ P.O. # _____

Activity _____ Date of Receipt _____

Location of Use _____

Contamination Survey

Counts per minute over 100 cm² area: _____ cpm

Efficiency of counting instrument: _____ %

Contamination level (dpm) = cpm / effic. = _____ dpm

Contamination level (μCi) = _____ dpm / 2.22 x 10⁶ d/μCi = _____ μCi

For C-14, I-125, S-35 Packages of 10 mCi or greater :

Radiation Levels at Surface (mR/hr) : _____

Radiation Levels at 1 Meter (mR/hr) : _____

Acceptable levels:	'1 Red Bar' Package	0.5 mR/hr at surface	background at 1 meter
	'2 Red Bars' Package	50 mR/hr at surface	1 mR/hr at 1 meter
	'3 Red Bars' Package	200 mR/hr at surface	10 mR/hr at 1 meter

Packages above acceptable limits are held for notification to vendor, shipper, and NRC. Contact the RSO immediately.

Date and Time of Delivery to User _____

User Signature _____

**Guidelines for Iodine-125 Iodinations
(and Tritium Experiments of >45 Millicuries)**

Iodine-125 emits 27-31 keV X-rays and a 35 keV gamma. Approximately 2 mm. of lead are required to completely attenuate I-125 in quantities typically used for iodinations. Iodine in the unbound state volatilizes readily and is efficiently taken into the body by inhalation or absorption through the skin. Approximately 30 percent of the activity taken in remains in the thyroid with an effective half life of about 40 days. Thus, the predominant concern on handling unbound iodine should be given to minimizing the contact with body.

1. Always work in a well-ventilated hood. Preplenum activated charcoal impregnated filters are recommended. A lucite inner hood (mini-hood) with a charcoal filter may be used. ERIBI provides a stainless steel isotope fume hood which is equipped with a continuous air sampler (Eberline RAS-1) installed in the duct system to evaluate release to the environment. The sampling cartridge will be evaluated semi-monthly initially. If data indicates minimal release, cartridges will be changed monthly. Charcoal filters will be installed in the duct if release data indicate that greater than 25% of the permissible level ($> 2 \times 10^{-11} \mu\text{C}/\text{cc}$ averaged over the sampling period) is being released. The sampling cartridges will be counted and evaluated by an independent radiation safety consultant. All reports will be forwarded to the RSO.

The cartridges themselves will be counted on a thin-crystal scintillation detector attached to a multichannel analyzer which has been calibrated for I-125.

Any tritium labelling experiments of greater than 45 mc will be sampled by pumping the effluent through a liquid collection system and counting an aliquot in a liquid scintillation counter. This result will also be compared to a materials balance performed by the investigator. All persons handling tritium will, in accordance with regulation, submit urine samples for bioassays within 48 hours.

2. Prepare a detailed written procedure for the iodination and submit it to the RSO for his approval. The procedure should be designed to minimize the opening of any vials through the use of syringe injection of material through septum topped vials. All containers of the radioactive material should be sealed in some manner, e.g., rubber stoppers, plastic cups or parafilm.
3. Conduct a dry (cold) run of the procedure to minimize the chance for error when the activity is used.

4. A baseline bioassay (either urine analysis, or preferably, a thyroid exam) should be done on anyone participating in the procedure. See reference 2 below.
5. Wear a personnel radiation dosimeter.
6. Wear the proper protective clothing, safety glasses and two layers of protective gloves. Iodine diffuses rapidly through vinyl and rubber so replace the outer layer immediately when it becomes contaminated. Keep the inner pair free of contamination.
7. Have a properly operating Geiger Muller survey instrument on and readily available for quick contamination checks. Be careful not to contaminate the instrument itself. The instrument will not detect very low levels of contamination but will be useful for higher levels.
8. Avoid handling the vials directly. Use remote handling devices such as tongs or forceps.
9. To decontaminate equipment or surfaces use a solution of 0.1M NaI, 0.1M NaOH, and 0.1M $\text{Na}_2\text{S}_2\text{O}_3$ in order to efficiently remove the contamination without releasing iodine to the atmosphere.
10. All waste should be sealed in double layers of plastic and disposed of immediately.
11. If exhaust filters are not used, the activity concentration of the exhaust must be monitored to assure compliance with NRC regulations concerning the release of Iodine-125 to the environment. See 10CFR20.103.
12. Clean and check all the working surfaces and equipment for contamination immediately after the procedure is finished. Take contamination wipes and count them with your samples. The survey instrument is useful for this work, but should not be used to perform the final check.
13. IT CANNOT BE EMPHASIZED TOO STRONGLY THAT NEAT, CAREFUL WORK HABITS WILL MINIMIZE BOTH CONTAMINATION PROBLEMS AND UNNECESSARY EXPOSURE TO PERSONNEL.

References

1. New England Nuclear Corp. Pamphlet: "Iodine-125 Guide to Safe Handling".
2. U.S. NRC Regulatory Guide 8.20 "Applications of Bioassay for I-125 and I-131".

Handling Procedures for Millicurie Quantities of Phosphorus-32

Phosphorus 32 emits a distribution of energetic beta particles, up to a maximum energy of 1.7 Mev, which can travel as far as 7 meters in air. The absorbed dose rate close to containers of millicurie quantities of P-32 is on the order rads/min. A significant fraction of P-32 entering the body deposits in the bone structure. The maximum permissible bone burden is 6 microcuries.

The following procedures should offer a guide to using sources of P-32 in excess of one millicurie.

1. Prepare a written set of procedures and submit them to the RSO for approval prior to the run.
2. Avoid handling the vial directly. Use remote handling tools, such as tongs or special holders when handling the source containers.
3. Use low density shielding (e.g. a minimum of 0.25 in. of plexiglass) to absorb the beta particles without generating significant amounts of X-rays by an interactive process called Bremsstrahlung. Heavy materials (high atomic number) should not be used close to the source because the Bremsstrahlung process is much more efficient for these materials. However, a small amount of lead on the outside of a plastic shield will absorb the Bremsstrahlung X-rays efficiently.
4. Wear Safety glasses to protect eyes from splashes and unnecessary radiation when working with more than 10 mCi.
5. Wear two sets of gloves; strip the outer pair off and replace if they become contaminated. Keep the inner pair clean at all times.
6. Have immediately available a properly operating G. M. detector for use in detecting contamination and radiation fields.
7. Wear personal dosimeter and finger dosimeters. The finger dosimeters are important because they will monitor the dose given to the fingers which the body dosimeter will not see.
8. Have your supervisor or the RSO observe during your first procedure.
9. After each procedure, survey the area with both the G. M. and wipes to eliminate any contamination.

Radioactive Waste Handling Procedures

Radioactive waste from experiments is taken from lab bench receptacles and put in the properly labeled 10 gallon galvanized cans located throughout the labs. When these cans are full, it is the responsibility of the Group Safety Coordinator to see that this radioactive waste is properly bagged, labeled and taken to the waste storage area. Experiments involving large amounts (200 micro curies) of radioisotope should be bagged, labeled and taken directly to the waste disposal area.

It is advised that each group leader make a duty roster of names for radioactive waste removal. In this way each scientist shares in the disposal burden and also shares in maintaining a safe environment.

SPECIFIC GUIDELINES FOR BAGGING WASTE

Persons handling radioactive waste should wear film badge, disposable gloves, and a lab coat. Persons should avoid working over the uncovered waste, since an uncovered direct path from a concentrated radioactive surface is not attenuated.

Make sure that dry waste is bagged in heavy duty polyethylene bags, the bags are tightly sealed, and labeled as the contents. Labels are available at the floor drop-off area.

The label should have the following filled out:

Category: On the back of the form are the possible categories. Label the tag 1 - 7 (see below) as it pertains to the contents. Liquid waste should be absorbed with absorbent material. This absorbent can be obtained from the RSO. Double the bags for scintillation vials. Cocktail can dissolve the bag.

Isotope: Enter isotope or isotopes in bag ^{32}P , ^{125}I , ^{35}S , ^3H or ^{14}C .

Chemical Name: dATP, dCTP, nucleotide, methionine, leucine, etc.

Activity (UA): Estimate on the high side the amount of activity in the bag.

Date: Enter today's date

Dept.: List your lab group/department

Bldg.: Enter 'ERIBI' and room number.

Packed By: Person who filled the bag, and their extension.

DISPOSAL CATEGORIES

There are seven categories of radioactive waste recognized at ERIBI. Waste must be bagged separately by category and labeled accordingly.

- 1) **³H and ¹⁴C Liquid Scintillation Vials.** Vials of these isotopes which have less than 100,000 cpm per vial on average. Double bag with no more than 200 20cc vials or 400 10cc vials per bag. This volume is about half of a 10 gallon can. (Disposal cost: \$130/30 gallon barrel.)
- 2) **Liquid Scintillation Vials - Other Isotopes.** Double bag, no limit to number of vials per bag. (Disposal cost: \$245/30 gallon barrel.)
- 3) **¹²⁵I and ¹³¹I Solid Waste.** Bag all solid waste together, both burnables and non-burnables. Waste is stored until it decays to background. (Disposal cost: \$90/30 gallon barrel.)
- 4) **Paper and Plastic (Burnable) Solid Waste.** Includes ³²P, ³⁵S, ³H, and ¹⁴C. Bag these isotopes together, but no metal or glass. (Disposal cost: \$90/30 gallon barrel.)
- 5) **³²P and ³⁵S Non-Burnable Solid Waste.** Bag these isotopes together but exclude paper and plastics. Barrels are stored until decayed and disposed of in garbage. (Disposal cost: \$90/30 gallon barrel.)
- 6) **³H and ¹⁴C Non-Burnable Solid Waste.** Bag together but exclude paper and plastic. (Disposal cost: \$245/30 gallon barrel. Shipped out of state.)
- 7) **Liquid Waste.** Most aqueous waste can be disposed of down a properly labeled and designated lab sink at the following rates per day. Amounts disposed must be recorded at the sink and total per sink per day cannot exceed unity (i.e., 50% of daily limit for ³²P and no more than 50% of daily limit for ¹²⁵I). See list below.

<u>Isotope</u>	<u>Daily Limit Per Sink</u>
³⁵ S	100 μ Ci
³² P	10 μ Ci
³ H	1mCi
¹⁴ C	100 μ Ci
¹²⁵ I	1 μ Ci

if the aqueous waste is significantly higher than the daily limits, they can be stored in separate containers (separated by isotope) and taken to the disposal storage area.

****NOTE****Use of absorbent for liquid ³H or ¹⁴C generates solid waste which is very bulky and must be shipped out of state at \$245 per barrel, so avoid this method of disposal whenever possible.

BE SURE TO ASK IF YOU HAVE ANY QUESTIONS ABOUT PROPER ISOTOPE HANDLING PROCEDURES.

THE FLOOR DISPOSAL SITES ARE REGULATED AND INSPECTED BY THE NRC. VIOLATION OF ANY OF THESE DISPOSAL PROCEDURES COULD RESULT IN THE SHUTDOWN OF THE FLOOR DISPOSAL FACILITY AND RESTRICTIONS ON FUTURE COMPANY USE OF ISOTOPES!

EISAI RESEARCH INSTITUTE OF BOSTON

Radioactive Material Inventory

Radioactive Material _____ User _____

Date Received _____ P.O. # _____

Date	Total Activity Present	Activity In Stock	Activity Stored As Waste	Activity Used in Exper.	Activity Shipped Out	Total Activity Remaining	User's Initials
_____	_____ = _____ + _____ - _____ - _____ = _____	_____	_____	_____	_____	_____	_____
_____	_____ = _____ + _____ - _____ - _____ = _____	_____	_____	_____	_____	_____	_____
_____	_____ = _____ + _____ - _____ - _____ = _____	_____	_____	_____	_____	_____	_____
_____	_____ = _____ + _____ - _____ - _____ = _____	_____	_____	_____	_____	_____	_____
_____	_____ = _____ + _____ - _____ - _____ = _____	_____	_____	_____	_____	_____	_____
_____	_____ = _____ + _____ - _____ - _____ = _____	_____	_____	_____	_____	_____	_____
_____	_____ = _____ + _____ - _____ - _____ = _____	_____	_____	_____	_____	_____	_____

EISAI RESEARCH INSTITUTE OF BOSTON

Radioactive Waste Inventory

Disposed of empty container: _____ User: _____

Date

Radioisotope

Activity

User

TOTALS: (To be completed when the radioactive waste is shipped.)

Radioisotope

Total Activity (mCi)

APPENDIX 5

NUCLEAR REGULATORY COMMISSION REGULATIONS AND GUIDES

10CFR20

10CFR19

Regulatory Guide 8.10

Regulaioy Guide 8.13



REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

(This page reissued
May 1977)

REGULATORY GUIDE 8.10

OPERATING PHILOSOPHY FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AS LOW AS IS REASONABLY ACHIEVABLE

A. INTRODUCTION

Paragraph 20.1(c) of 10 CFR Part 20, "Standards for Protection Against Radiation," states, in part, that licensees should make every reasonable effort to maintain radiation exposures as far below the limits specified in that part as practicable. This guide describes to licensees a general operating philosophy acceptable to the NRC staff as a necessary basis for a program of maintaining occupational exposures to radiation as low as is reasonably achievable.

Both this guide and Regulatory Guide 8.8, "Information Relevant to Maintaining Occupational Radiation Exposure as Low as is Reasonably Achievable (Nuclear Power Reactors)," deal with the concept of "as low as is reasonably achievable" occupational exposures to radiation. The main difference between the two guides, aside from the fact that Regulatory Guide 8.8 applies only to nuclear power reactors and this guide applies to all specific licensees, is that Regulatory Guide 8.8 is addressed to applicants for a license and tells them what information relevant to "as low as is reasonably achievable" should be included in their license applications. This guide, on the other hand, describes an operating philosophy that the NRC staff believes all specific licensees should follow to keep occupational exposures to radiation as low as is reasonably achievable.

B. DISCUSSION

Even though current occupational exposure limits provide a very low risk of injury, it is prudent to avoid unnecessary exposure to radiation. The objective is thus to reduce occupational exposures as far below the specified limits as is reasonably achievable by means of good radiation protection planning and practice, as well as by management commitment to policies that foster vigilance against departures from good practice.

In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals should also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

C. REGULATORY POSITION

Two basic conditions are considered necessary in any program for keeping occupational exposures as far below the specified limits as is reasonably achievable. The management of the licensed facility should be committed to maintaining exposures as low as is reasonably achievable, and the personnel responsible for radiation protection should be continually vigilant for means to reduce exposures.

1. Management Commitment

The commitment made by licensee management to minimize exposures should provide clearly defined radiation protection responsibilities and an environment in which the radiation protection staff can do its job properly. There are several aspects to this commitment:

a. **Plant personnel should be made aware of management's commitment to keep occupational exposures as low as is reasonably achievable.** The commitment should appear in policy statements, instructions to personnel, and similar documents. As a minimum, workers should be sufficiently familiar with this commitment that they can explain what the management commitment is, what "as low as is reasonably achievable exposure to radiation" means, why it is recommended, and how they have been advised to implement it on their jobs.

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. However, the staff's consideration of comments received during the initial public comment period for this guide has resulted in the determination that there is no need for a revision at this time.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

The guides are issued in the following ten broad divisions:

- | | |
|-----------------------------------|------------------------|
| 1. Power Reactors | 6. Products |
| 2. Research and Test Reactors | 7. Transportation |
| 3. Fuels and Materials Facilities | 8. Occupational Health |
| 4. Environmental and Siting | 9. Antitrust Review |
| 5. Materials and Plant Protection | 10. General |

Requests for single copies of issued guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Document Control.

b. Management should periodically perform a formal audit to determine how exposures might be lowered. This should include reviews of operating procedures and past exposure records, plant inspections, and consultations with the radiation protection staff or outside consultants. As a minimum, management should be able to discuss which operating procedures were reviewed, in which locations most exposures are being received, what groups of workers are receiving the highest exposures, what discussions they have had with the radiation protection staff or outside consultants, and what steps they have taken to reduce exposures.

c. The management should ensure that there is a well-supervised radiation protection capability with well-defined responsibilities. The qualifications for the Radiation Protection Manager for a nuclear power reactor facility are presented in Regulatory Guides 1.8 and 8.8. Applicants submitting applications for any specific license other than a nuclear power reactor license should select and state the qualifications for the lead individual who will be responsible for implementing the radiation protection program for the facility, i.e., the Radiation Safety Officer (RSO).¹ The qualifications selected should be commensurate with the potential problems anticipated to be encountered in a facility of the type subject to the license.

d. The management should see that plant workers receive sufficient training. Section 19.12 of 10 CFR Part 19 requires instruction of personnel on radiation protection. The radiation worker should understand how radiation protection relates to his job and should be tested on this understanding at least once per year. He should have frequent opportunities to discuss radiation safety with the radiation protection staff whenever the need arises. Management should be committed to a review of radiation protection at least once every three years. Training should be sufficient to ensure that the workers can correctly answer questions on radiation protection as it relates to their jobs.

e. The RSO should be given sufficient authority to enforce safe plant operation. The RSO should have the authority to prevent unsafe practices and to communicate promptly with an appropriate level of management about halting an operation he deems unsafe. Operating procedures related to radiation safety should be reviewed and approved by radiation protection personnel. This authority should be demonstrable by written policy statements.

f. Modifications to operating and maintenance procedures and to plant equipment and facilities should be made where they will substantially reduce exposures at a reasonable cost. The management should be able to

demonstrate that improvements have been sought, that modifications have been considered, and that they have been implemented where practicable. Where modifications have been considered but not implemented, the licensee should be prepared to describe the reasons for not implementing them.

2. Vigilance by the RSO and the Radiation Protection Staff

It should be the responsibility of the RSO and the radiation protection staff to conduct surveillance programs and investigations to ensure that occupational exposures are as far below the specified limits as is reasonably achievable. Additionally, they should be vigilant in searching out new and better ways to perform all radiation jobs with less exposure. There are several aspects to this responsibility.

a. The RSO and the radiation protection staff should know the origins of radiation exposures in the plant. They should know these by location, operation, and job category and should be aware of trends in exposures. Where radiation work permits are used, exposures received should be recorded on the permits. The RSO and the radiation protection staff should be able to describe which locations, operations, and jobs are associated with the highest exposures and why exposures are increasing or decreasing.

b. The RSO and the radiation protection staff should look for ways to reduce exposures. When unusual exposures have occurred, the radiation protection staff should direct and participate in an investigation of the circumstances of such exposures to determine the causes and take steps to reduce the likelihood of similar future occurrences. For each such occurrence, the RSO should be able to demonstrate that such an investigation has been carried out, that conclusions were reached as a result of the investigation, and that corrective action was taken, as appropriate.

The RSO and the radiation protection staff should periodically review operating procedures that may affect radiation safety and survey plant operations to identify situations in which exposures can be reduced. Indicated changes should be promptly implemented. Procedures for receiving and evaluating suggestions relating to radiation protection from employees should be established. Workers should be knowledgeable of the procedures for making suggestions on radiation protection.

c. Adequate equipment and supplies for radiation protection work should be provided. The RSO should be responsible for ensuring that proper equipment and supplies are available, are maintained in good working order, and are used properly. Written procedures for the use of the equipment should be available and followed.

*Lines indicate substantive changes from previous issue.

¹The term "Radiation Safety Officer" is used by many licensees; other terms are equally acceptable.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for utilizing this regulatory guide.

Except in those cases in which the applicant or licensee proposes an alternative method for complying

with the specified portions of the Commission's regulations, the methods described herein will be used in the evaluation of submittals in connection with applications for a specific license.

Regulatory Guides 1.8 and 8.8 address nuclear power reactor facilities specifically and will be used by the NRC staff in evaluating submittals in connection with licensing actions for nuclear power reactors.



REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.13
(Task OP 0314)

INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

Section 19.12, "Instructions to Workers," of 10 CFR Part 19, "Notices, Instructions, and Reports to Workers; Inspections," requires that all individuals working in or frequenting any portion of a restricted area¹ be instructed in the health protection problems associated with exposure to radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the regulations that they are expected to observe. The present 10 CFR Part 20, "Standards for Protection Against Radiation," has no special limit for exposure of the embryo/fetus.² This guide describes the instructions an employer should provide to workers and supervisors concerning biological risks to the embryo/fetus exposed to radiation, a dose limit for the embryo/fetus that is under consideration, and suggestions for reducing radiation exposure.

This regulatory guide takes into consideration a proposed revision to 10 CFR Part 20, which incorporates the radiation protection guidance for the embryo/fetus approved by the President in January 1987 (Ref. 1). This revision to Part 20 was issued in January 1986 for comment as a proposed rule. Comments on the guide as it pertains to the proposed Part 20 are encouraged. If the new Part 20 is codified, this regulatory guide will be revised to conform to the new regulation and will incorporate appropriate public comments.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Parts 19 or 20, which provide the regulatory

¹Restricted area means any area that has controlled access to protect individuals from being exposed to radiation and radioactive materials.

²In conformity with the proposed revision to 10 CFR Part 20, the term "embryo/fetus" is used throughout this document to represent all stages of pregnancy.

basis for this guide. The information collection requirements in 10 CFR Parts 19 and 20 have been cleared under OMB Clearance Nos. 3150-0044 and 3150-0014, respectively.

B. DISCUSSION

It has been known since 1906 that cells that are dividing very rapidly and are undifferentiated in their structure and function are generally more sensitive to radiation. In the embryo stage, cells meet both these criteria and thus would be expected to be highly sensitive to radiation. Furthermore, there is direct evidence that the embryo/fetus is radiosensitive. There is also evidence that it is especially sensitive to certain radiation effects during certain periods after conception, particularly during the first 2 to 3 months after conception when a woman may not be aware that she is pregnant.

Section 20.104 of 10 CFR Part 20 places different radiation dose limits on workers who are minors than on adult workers. Workers under the age of 18 are limited to one-tenth of the adult radiation dose limits. However, the present NRC regulations do not establish dose limits specifically for the embryo/fetus.

The NRC's present limit on the radiation dose that can be received on the job is 1,250 millirems per quarter (3 months).³ Working minors (those under 18) are limited to a dose equal to one-tenth that of adults, 125 millirems per quarter. (See § 20.101 of 10 CFR Part 20.)

Because of the sensitivity of the unborn child, the National Council on Radiation Protection and Measurements (NCRP) has recommended that the dose equivalent

³The limit is 3,000 millirems per quarter if the worker's occupational dose history is known and the average dose does not exceed 5,000 millirems per year.

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

Written comments may be submitted to the Rules and Procedures Branch, DRR, ADM, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The guides are issued in the following ten broad divisions:

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|-----------------------------------|-----------------------------------|
| 1. Power Reactors | 6. Products |
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Issued guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161.

to the unborn child from occupational exposure of the expectant mother be limited to 500 millirems for the entire pregnancy (Ref. 2). The 1987 Presidential guidance (Ref. 1) specifies an effective dose equivalent limit of 500 millirems to the unborn child if the pregnancy has been declared by the mother; the guidance also recommends that substantial variations in the rate of exposure be avoided. The NRC (in § 20.208 of its proposed revision to Part 20) has proposed adoption of the above limits on dose and rate of exposure.

In 1971, the NCRP commented on the occupational exposure of fertile women (Ref. 2) and suggested that fertile women should be employed only where the annual dose would be unlikely to exceed 2 or 3 rems and would be accumulated at a more or less steady rate. In 1977, the ICRP recommended that, when pregnancy has been diagnosed, the woman work only where it is unlikely that the annual dose would exceed 0.30 of the dose-equivalent limit of 5 rems (Ref. 3). In other words, the ICRP has recommended that pregnant women not work where the annual dose might exceed 1.5 rem.

C. REGULATORY POSITION

Instructions on radiation risks should be provided to workers, including supervisors, in accordance with § 19.12 of 10 CFR Part 19 before they are allowed to work in a restricted area. In providing instructions on radiation risks, employers should include specific instruc-

tions about the risks of radiation exposure to the embryo/fetus.

The instructions should be presented both orally and in printed form, and the instructions should include, as a minimum, the information provided in Appendix A (Instructor's Guide) to this guide. Individuals should be given the opportunity to ask questions and in turn should be questioned to determine whether they understand the instructions. An acceptable method of ensuring that the information is understood is to give a simple written test covering the material included in Appendix B (Pregnant Worker's Guide). This approach should highlight for instructors those parts of the instructions that cause difficulties and thereby lead to appropriate modifications in the instructional curriculum.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant or licensee proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the NRC will use the material described in this guide to evaluate the instructional program presented to individuals, including supervisors, working in or frequenting any portion of a restricted area.

APPENDIX A

INSTRUCTOR'S GUIDE

EFFECTS ON THE EMBRYO/FETUS OF EXPOSURE TO RADIATION AND OTHER ENVIRONMENTAL HAZARDS

In order to decide whether to continue working while exposed to ionizing radiation during her pregnancy, a woman should understand the potential effects on an embryo/fetus, including those that may be produced by various environmental risks such as smoking and drinking. This will allow her to compare these risks with those produced by exposure to ionizing radiation.

Table 1 provides information on the potential effects resulting from exposure of an embryo/fetus to radiation and nonradiation risks. The second column gives the rate at which the effect is produced by natural causes in terms of the number per thousand cases. The fourth column gives the number of additional effects per thousand cases believed to be produced by exposure to the specified amount of the risk factor.

The following section discusses the studies from which the information in Table 1 was derived. The results of exposure of the embryo/fetus to the risk factors and the dependence on the amount of the exposure are explained.

1. RADIATION RISKS

1.1 Childhood Cancer

Numerous studies of radiation-induced childhood cancer have been performed, but a number of them are controversial. The National Academy of Science (NAS) BEIR report reevaluated the data from these studies and even reanalyzed the results. Some of the strongest support for a causal relationship is provided by twin data from the Oxford survey (Ref. 4). For maternal radiation doses of 1,000 millirems, the excess number of deaths (above those occurring from natural causes) was found to be 0.6 death per thousand children (Ref. 4).

1.2 Mental Retardation and Abnormal Smallness of the Head (Microcephaly)

Studies of Japanese children who were exposed while in the womb to the atomic bomb radiation at Hiroshima and Nagasaki have shown evidence of both small head size and mental retardation. Most of the children were exposed to radiation doses in the range of 1 to 50 rads. The importance of the most recent study lies in the fact that investigators were able to show that the gestational age (age of the embryo/fetus after conception) at the time the children were exposed was a critical factor (Ref. 7). The approximate risk of small head size as a function of gestational age is shown in Table 1. For a radiation dose of 1,000 millirems at 4 to 7 weeks after conception, the

excess cases of small head size was 5 per thousand; at 8 to 11 weeks, it was 9 per thousand (Ref. 7).

In another study, the highest risk of mental retardation occurred during the 8 to 15 week period after conception (Ref. 8). A recent EPA study (Ref. 16) has calculated that excess cases of mental retardation per live birth lie between 0.5 and 4 per thousand per rad.

1.3 Genetic Effects

Radiation-induced genetic effects have not been observed to date in humans. The largest source of material for genetic studies involves the survivors of Hiroshima and Nagasaki, but the 77,000 births that occurred among the survivors showed no evidence of genetic effects. For doses received by the pregnant worker in the course of employment considered in this guide, the dose received by the embryo/fetus apparently would have a negligible effect on descendants (Refs. 17 and 18).

2. NONRADIATION RISKS

2.1 Occupation

A recent study (Ref. 9) involving the birth records of 130,000 children in the State of Washington indicates that the risk of death to the unborn child is related to the occupation of the mother. Workers in the metal industry, the chemical industry, medical technology, the wood industry, the textile industry, and farms exhibited stillbirths or spontaneous abortions at a rate of 90 per thousand above that of workers in the control group, which consisted of workers in several other industries.

2.2 Alcohol

It has been recognized since ancient times that alcohol consumption had an effect on the unborn child. Carthaginian law forbade the consumption of wine on the wedding night so that a defective child might not be conceived. Recent studies have indicated that small amounts of alcohol consumption have only the minor effect of reducing the birth weight slightly, but when consumption increases to 2 to 4 drinks per day, a pattern of abnormalities called the fetal alcohol syndrome (FAS) begins to appear (Ref. 11). This syndrome consists of reduced growth in the unborn child, faulty brain function, and abnormal facial features. There is a syndrome that has the same symptoms as full-blown FAS that occurs in children born to mothers who have not consumed alcohol. This naturally occurring syndrome occurs in about 1 to 2 cases per thousand (Ref. 10).

TABLE 1

EFFECTS OF RISK FACTORS ON PREGNANCY OUTCOME

Effect	Number Occurring from Natural Causes	Risk Factor	Excess Occurrences from Risk Factor
RADIATION RISKS			
Childhood Cancer			
Cancer death in children	1.4 per thousand (Ref. 5)	Radiation dose of 1000 millirems received before birth	0.6 per thousand (Ref. 4)
Abnormalities			
Radiation dose of 1000 millirads received during specific periods after conception:			
Small head size	40 per thousand (Ref. 6)	4-7 weeks after conception	5 per thousand (Ref. 7)
Small head size	40 per thousand (Ref. 6)	8-11 weeks after conception	9 per thousand (Ref. 7)
Mental retardation	4 per thousand (Ref. 8)	Radiation dose of 1000 millirads received 8 to 15 weeks after conception	4 per thousand (Ref. 8)
NONRADIATION RISKS			
Occupation			
Stillbirth or spontaneous abortion	200 per thousand (Ref. 9)	Work in high-risk occupations (see text)	90 per thousand (Ref. 9)
Alcohol Consumption (see text)			
Fetal alcohol syndrome	1 to 2 per thousand (Ref. 10)	2-4 drinks per day	100 per thousand (Ref. 11)
Fetal alcohol syndrome	1 to 2 per thousand (Ref. 10)	More than 4 drinks per day	200 per thousand (Ref. 11)
Fetal alcohol syndrome	1 to 2 per thousand (Ref. 10)	Chronic alcoholic (more than 10 drinks per day)	350 per thousand (Ref. 12)
Perinatal infant death (around the time of birth)	23 per thousand (Refs. 13, 14)	Chronic alcoholic (more than 10 drinks per day)	170 per thousand (Ref. 15)
Smoking			
Perinatal infant death	23 per thousand (Refs. 13, 14)	Less than 1 pack per day	5 per thousand (Ref. 13)
Perinatal infant death	23 per thousand (Refs. 13, 14)	One pack or more per day	10 per thousand (Ref. 13)

For mothers who consume 2 to 4 drinks per day, the excess occurrences number about 100 per thousand; and for those who consume more than 4 drinks per day, excess occurrences number 200 per thousand. The most sensitive period for this effect of alcohol appears to be the first few weeks after conception, before the mother-to-be realizes she is pregnant (Refs. 10 and 11). Also, 17% or 170 per thousand of the embryo/fetuses of chronic alcoholics develop FAS and die before birth (Ref. 15). FAS was first identified in 1973 in the United States where less than full-blown effects of the syndrome are now referred to as fetal alcohol effects (FAE) (Ref. 12).

2.3 Smoking

Smoking during pregnancy causes reduced birth weights in babies amounting to 5 to 9 ounces on the average. In addition, there is an increased risk of 5 infant deaths per thousand for mothers who smoke less than one pack per day and 10 infant deaths per

thousand for others who smoke one or more packs per day (Ref. 13).

2.4 Miscellaneous

Numerous other risks affect the embryo/fetus, only a few of which are touched upon here. Most people are familiar with the drug thalidomide (a sedative given to some pregnant women), which causes children to be born with missing limbs, and the more recent use of the drug diethylstilbestrol (DES), a synthetic estrogen given to some women to treat menstrual disorders, which produced vaginal cancers in the daughters born to women who took the drug. Living at high altitudes also gives rise to an increase in the number of low-birth-weight children born, while an increase in Down's Syndrome (mongolism) occurs in children born to mothers who are over 35 years of age. The rapid growth in the use of ultrasound in recent years has sparked an ongoing investigation into the risks of using ultrasound for diagnostic procedures (Ref. 19).

APPENDIX B

PREGNANT WORKER'S GUIDE

POSSIBLE HEALTH RISKS TO CHILDREN OF WOMEN WHO ARE EXPOSED TO RADIATION DURING PREGNANCY

During pregnancy, you should be aware of things in your surroundings or in your style of life that could affect your unborn child. For those of you who work in or visit areas designated as Restricted Areas (where access is controlled to protect individuals from being exposed to radiation and radioactive materials), it is desirable that you understand the biological risks of radiation to your unborn child.

Everyone is exposed daily to various kinds of radiation: heat, light, ultraviolet, microwave, ionizing, and so on. For the purposes of this guide, only ionizing radiation (such as x-rays, gamma rays, neutrons, and other high-speed atomic particles) is considered. Actually, everything is radioactive and all human activities involve exposure to radiation. People are exposed to different amounts of natural "background" ionizing radiation depending on where they live. Radon gas in homes is a problem of growing concern. Background radiation comes from three sources:

	Average Annual Dose
Terrestrial - radiation from soil and rocks	50 millirem
Cosmic - radiation from outer space	50 millirem
Radioactivity normally found within the human body	25 millirem
	125 millirem*
Dosage range (geographic and other factors)	75 to 5,000 millirem

The first two of these sources expose the body from the outside, and the last one exposes it from the inside. The average person is thus exposed to a total dose of about 125 millirems per year from natural background radiation.

In addition to exposure from normal background radiation, medical procedures may contribute to the dose people receive. The following table lists the average doses received by the bone marrow (the blood-forming cells) from different medical applications.

*Radiation doses in this document are described in two different units. The rad is a measure of the amount of energy absorbed in a certain amount of material (100 ergs per gram). Equal amounts of energy absorbed from different types of radiation may lead to different biological effects. The rem is a unit that reflects the biological damage done to the body. The millirad and millirem refer to 1/1000 of a rad and a rem, respectively.

<u>X-Ray Procedure</u>	<u>Average Dose*</u>
Normal chest examination	10 millirem
Normal dental examination	10 millirem
Rib cage examination	140 millirem
Gall bladder examination	170 millirem
Barium enema examination	500 millirem
Pelvic examination	600 millirem

*Variations by a factor of 2 (above and below) are not unusual.

NRC POSITION

NRC regulations and guidance are based on the conservative assumption that any amount of radiation, no matter how small, can have a harmful effect on an adult, child, or unborn child. This assumption is said to be conservative because there are no data showing ill effects from small doses; the National Academy of Sciences recently expressed "uncertainty as to whether a dose of, say, 1 rad would have any effect?" Although it is known that the unborn child is more sensitive to radiation than adults, particularly during certain stages of development, the NRC has not established a special dose limit for protection of the unborn child. Such a limit could result in job discrimination for women of child-bearing age and perhaps in the invasion of privacy (if pregnancy tests were required) if a separate regulatory dose limit were specified for the unborn child. Therefore, the NRC has taken the position that special protection of the unborn child should be *voluntary* and should be based on decisions made by workers and employers who are well informed about the risks involved.

For the NRC position to be effective, it is important that both the employee and the employer understand the risk to the unborn child from radiation received as a result of the occupational exposure of the mother. This document tries to explain the risk as clearly as possible and to compare it with other risks to the unborn child during pregnancy. It is hoped this will help pregnant employees balance the risk to the unborn child against the benefits of employment to decide if the risk is worth taking. This document also discusses methods of keeping the dose, and therefore the risk, to the unborn child as low as is reasonably achievable.

RADIATION DOSE LIMITS

The NRC's present limit on the radiation dose that can be received on the job is 1,250 millirems per quarter (3 months).^{*} Working minors (those under 18) are limited to a dose equal to one-tenth that of adults, 125 millirems per quarter. (See § 20.101 of 10 CFR Part 20.)

Because of the sensitivity of the unborn child, the National Council on Radiation Protection and Measurements (NCRP) has recommended that the dose equivalent to the unborn child from occupational exposure of the expectant mother be limited to 500 millirems for the entire pregnancy (Ref. 2). The 1987 Presidential guidance (Ref. 1) specifies an effective dose equivalent limit of 500 millirems to the unborn child if the pregnancy has been declared by the mother; the guidance also recommends that substantial variations in the rate of exposure be avoided. The NRC (in § 20.208 of its proposed revision to Part 20) has proposed adoption of the above limits on dose and rate of exposure.

ADVICE FOR EMPLOYEE AND EMPLOYER

Although the risks to the unborn child are small under normal working conditions, it is still advisable to limit the radiation dose from occupational exposure to no more than 500 millirems for the total pregnancy. Employee and employer should work together to decide the best method for accomplishing this goal. Some methods that might be used include reducing the time spent in radiation areas, wearing some shielding over the abdominal area, and keeping an extra distance from radiation sources when possible. The employer or health physicist will be able to estimate the probable dose to the unborn child during the normal nine-month pregnancy period and to inform the employee of the amount. If the predicted dose exceeds 500 millirems, the employee and employer should work out schedules or proce-

^{*} The limit is 3,000 millirems per quarter if the worker's occupational dose history is known and the average dose does not exceed 5,000 millirems per year.

dures to limit the dose to the 500-millirem recommended limit.

It is important that the employee inform the employer of her condition as soon as she realizes she is pregnant if the dose to the unborn child is to be minimized.

INTERNAL HAZARDS

This document has been directed primarily toward a discussion of radiation doses received from sources outside the body. Workers should also be aware that there is a risk of radioactive material entering the body in workplaces where unsealed radioactive material is used. Nuclear medicine clinics, laboratories, and certain manufacturers use radioactive material in bulk form, often as a liquid or a gas. A list of the commonly used materials and safety precautions for each is beyond the scope of this document, but certain general precautions might include the following:

1. Do not smoke, eat, drink, or apply cosmetics around radioactive material.
2. Do not pipette solutions by mouth.
3. Use disposable gloves while handling radioactive material when feasible.
4. Wash hands after working around radioactive material.
5. Wear lab coats or other protective clothing whenever there is a possibility of spills.

Remember that the employer is required to have demonstrated that it will have safe procedures and practices before the NRC issues it a license to use radioactive material. Workers are urged to follow established procedures and consult the employer's radiation safety officer or health physicist whenever problems or questions arise.

REFERENCES

1. "Federal Radiation Protection Guidance for Occupational Exposure," *Federal Register*, p. 2822, January 27, 1987.
2. National Council on Radiation Protection and Measurements, "Basic Radiation Protection Criteria," NCRP Report No. 39, 1971.
3. International Commission on Radiological Protection, "Recommendations of the International Commission on Radiological Protection," ICRP Publication No. 26, Vol. 1, No. 3, 1977.
4. National Academy of Sciences, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation (BEIR III)," National Academy Press, Washington, DC, 1980.
5. J. L. Young and R. W. Miller, "Incidence of Malignant Tumors in U.S. Children," *Journal of Pediatrics*, pp. 254-258, 1975.
6. W. J. Blot, "Growth and Development Following Prenatal and Childhood Exposure to Atomic Radiation," *Journal of Radiation Research* (Supplement), pp. 82-85, 1975.
7. R. W. Miller and J. J. Mulvihill, "Small Head Size After Atomic Radiation," *Teratology*, Vol. 14, pp. 355-358, 1976.
8. M. Otake and W. J. Schull, "In Utero Exposure to A-bomb Radiation and Mental Retardation; a Reassessment," *The British Journal of Radiology*, Vol. 57, pp. 409-414, 1984.
9. T. L. Vaughan et al., "Fetal Death and Maternal Occupation," *Journal of Occupational Medicine*, Vol. 26, No. 9, pp. 676-678, 1984.
10. J. W. Hanson, A. P. Streissguth, and D. W. Smith, "The Effects of Moderate Alcohol Consumption During Pregnancy on Fetal Growth and Morphogenesis," *Journal of Pediatrics*, Vol. 92, pp. 457-460, 1978.
11. D. W. Smith, "Alcohol Effects on the Fetus," *Progress in Clinical and Biological Research*, Vol. 36, pp. 73-82, 1980.
12. L. B. Robe, "Alcohol and Pregnancy," The American Medical Association, Box 10946, Chicago, 1984.
13. M. B. Meyer and J. A. Tonascia, "Maternal Smoking, Pregnancy Complications, and Perinatal Mortality," *American Journal of Obstetrics and Gynecology*, Vol. 128, No. 5, pp. 494-502, 1977.
14. R. H. Mole, "Radiation Effects on Pre-Natal Development and Their Radiological Significance," *The British Journal of Radiology*, Vol. 52, No. 614, pp. 89-101, February 1979.
15. D. A. Roe, *Alcohol and the Diet*, AVI Publishing Company Inc., Westport, Connecticut, 1979.
16. Environmental Protection Agency, "Radionuclides," Background Information Document EPA 520/1-84-022-1, pp. 8-56 - 8-63.
17. G. W. Beebe, "The Atomic Bomb Survivors and the Problem of Low-Dose Radiation Effects," *American Journal of Epidemiology*, Vol. 114, No. 6, pp. 761-783, 1981.
18. W. J. Blot et al., "Reproductive Potential of Maies Exposed in Utero or Prepubertally to Atomic Radiation," in *Atomic Bomb Casualty Commission Technical Report TR-39-72*, Radiation Effects Research Foundation, Hiroshima, Japan, 1972.
19. National Council on Radiation Protection and Measurements, "Protection in Nuclear Medicine and Ultrasound Diagnostic Procedures in Children," NCRP Report No. 73, 1983.

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS - ENERGY

§ 19.1

§ 19.12

**PART
19**

**NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS;
INSPECTIONS**

Sec.

- 19.1 Purpose.
- 19.2 Scope.
- 19.3 Definitions.
- 19.4 Interpretations.
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- 19.8 Information collection requirements:
OMB approval.
- 19.11 Posting of notices to workers.
- 19.12 Instructions to workers.
- 19.13 Notifications and reports to individuals.
- 19.14 Presence of representatives of licensees and workers during inspections.
- 19.15 Consultation with workers during inspections.
- 19.16 Requests by workers for inspections.
- 19.17 Inspections not warranting informal review.
- 19.30 Violations.
- 19.31 Application for exemptions.
- 19.32 Discrimination prohibited.

Authority: Secs. 53, 63, 61, 103, 104, 161, 166, 66 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2073, 2083, 2111, 2133, 2134, 2201, 2236, 2282); sec. 201, 86 Stat. 1242, as amended by Pub. L. 94-79, 89 Stat. 413 (42 U.S.C. 5841), Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851).

For the purposes of sec. 223, 66 Stat. 956, as amended (42 U.S.C. 2273); §§ 19.11(a), (c), (d), and (e) and 19.12 are issued under sec. 161b, 66 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 19.13 and 19.14(a) are issued under sec. 161c, 66 Stat. 950, as amended (42 U.S.C. 2201(c)).

§ 19.1 Purpose.

The regulations in this part establish requirements for notices, instructions, and reports by licensees to individuals participating in licensed activities, and options available to such individuals in connection with Commission inspections of licensees to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, Title II of the Energy Reorganization Act of 1974, and regulations, orders, and licenses thereunder regarding radiological working conditions.

§ 19.2 Scope.

The regulations in this part apply to all persons who receive, possess, use, or transfer material licensed by the Nuclear Regulatory Commission pursuant to the regulations in Parts 30 through 35, 40, 60, 61, 70 or 72 of this chapter, including persons licensed to operate a production or utilization facility pursuant to Part 50 of this chapter and persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter.

§ 19.3 Definitions.

As used in this part:
(a) "Act" means the Atomic Energy Act of 1954, (68 Stat. 919) including any amendments thereto;

(b) "Commission" means the United States Nuclear Regulatory Commission;

(c) "Worker" means an individual engaged in activities licensed by the Commission and controlled by a licensee, but does not include the licensee

(d) "License" means a license issued under the regulations in Parts 30 through 35, 40, 60, 61, 70 or 72 of this chapter, including licenses to operate a production or utilization facility pursuant to Part 50 of this chapter and licenses to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter. "Licensee" means the holder of such a license.

(e) "Restricted area" means any area access to which is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. "Restricted area" shall not include any areas used as residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

§ 19.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 19.5 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Communications, reports, and applications may be delivered in person at the Commission's offices at 1717 H Street, NW, Washington, D.C.; or at 7920 Norfolk Avenue, Bethesda, Maryland.

§ 19.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control

number 3150-0044.

(b) The approved information collection requirements contained in this part appear in § 19.13.

§ 19.11 Posting of notices to workers.

(a) Each licensee shall post current copies of the following documents: (1) The regulations in this part and in Part 20 of this chapter; (2) the license, license conditions, or documents incorporated into a license by reference, and amendments thereto; (3) the operating procedures applicable to licensed activities; (4) any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Subpart B of Part 2 of this chapter, and any response from the licensee.

(b) If posting of a document specified in paragraph (a) (1), (2) or (3) of this section is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

(c) Each licensee and applicant shall post Form NRC-3, (Revision 5-82 or later) "Notice to Employees," as required by Parts 30, 40, 50, 60, 70, 72, and 150 of this chapter.

NOTE: Copies of Form NRC-3 may be obtained by writing to the Director of the appropriate U.S. Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix "D", Part 20 of this chapter, or the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(d) Documents, notices, or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(e) Commission documents posted pursuant to paragraph (a) (4) of this section shall be posted within 2 working days after receipt of the documents from the Commission; the licensee's response, if any, shall be posted within 2 working days after dispatch by the licensee. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

§ 19.12 Instructions to workers.

All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer, or use of radioactive materials or of radiation in such portions of the restricted area; shall be instructed in the health protection problems associated

PART 19 • NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radiation or radioactive materials occurring in such areas; shall be instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation or to radioactive material; shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and shall be advised as to the radiation exposure reports which workers may request pursuant to § 19.13. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

§ 19.13 Notifications and reports to individuals.

(a) Radiation exposure data for an individual, and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Commission regulations, orders or license conditions, as shown in records maintained by the licensee pursuant to Commission regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the following statement:

This report is furnished to you under the provisions of the Nuclear Regulatory Commission regulation 10 CFR Part 19. You should preserve this report for further reference.

(b) At the request of any worker, each licensee shall advise such worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee pursuant to § 20.401(a) and (c).

(c) At the request of a worker formerly engaged in licensed activities controlled by the licensee, each licensee shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive materials licensed by the Commission; and shall include the dates and locations of licensed activities in which the worker participated during this period.

(d) When a licensee is required pursuant to § 20.405 or § 20.408 of this chapter to report to the Commission any exposure of an individual to radiation or radioactive material the licensee shall also provide the individual a report on his exposure data included therein. Such report shall be transmitted at a time not later than the transmittal to the Commission.

(e) At the request of a worker who is terminating employment in a given calendar quarter with the licensee in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's facility in that calendar quarter, each licensee shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee during that specifically identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such.

§ 19.14 Presence of representatives of licensees and workers during inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records pursuant to the regulations in this chapter.

(b) During an inspection, Commission inspectors may consult privately with workers as specified in § 19.15. The licensee or licensee's representative may accompany Commission inspectors during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Commission inspections, the licensee shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in licensed activities under control of the licensee and shall have received instructions as specified in § 19.12.

(e) Different representatives of licensees and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee and the workers' representative an individual who is not routinely engaged in licensed activities under control of the licensee, for example, a consultant to the licensee or to the workers' representative, shall be afforded the opportunity to accompany Commission inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provi-

sions of this section, Commission inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee to enter that area.

§ 19.15 Consultation with workers during inspections.

(a) Commission inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Commission regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the act, the regulations in this chapter, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material under the licensee's control. Any such notice in writing shall comply with the requirements of § 19.16(a).

(c) The provisions of paragraph (b) of this section shall not be interpreted as authorization to disregard instructions pursuant to § 19.12.

§ 19.16 Requests by workers for inspections.

(a) Any worker or representative of workers who believes that a violation of the Act, the regulations in this chapter, or license conditions exists or has occurred in license activities with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Director of Inspection and Enforcement, to the Director of the appropriate Commission Regional Office, or to Commission inspectors. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of workers. A copy shall be provided the licensee by the Director of Inspection and Enforcement, Regional Office Director,

or the inspector no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Commission, except for good cause shown.

(b) If, upon receipt of such notice, the Director of Inspection and Enforcement or Regional Office Director determines that the complaint meets the requirements set forth in paragraph (a) of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pur-

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suant to this section need not be limited to matters referred to in the complaint.

§ 19.17 Inspections not warranted; informal review.

(a) If the Director of Inspection and Enforcement or of the appropriate Regional Office determines, with respect to a complaint under § 19.16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, he shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, who will provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee may submit an opposing written statement of position with the Executive Director for Operations who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Executive Director for Operations or his designee may

hold an informal conference in which the complainant and the licensee may orally present their views. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Executive Director for Operations shall affirm, modify, or reverse the determination of the Director of Inspection and Enforcement or of the appropriate Regional Office and furnish the complainant and the licensee a written notification of his decision and the reason therefor.

(b) If the Director of Inspection and Enforcement or of the appropriate Regional Office determines that an inspection is not warranted because the requirements of § 19.16(a) have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of § 19.16(a).

§ 19.30 Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or Title II of the Energy Reorganization Act of 1974, or any regulation or order issued thereunder.

A court order may be obtained for the payment of a civil penalty imposed pursuant to section 234 of the Act for violation of section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act or any rule, regulation, or order issued thereunder, or any term, condition or limitation of any license issued thereunder, or for any violation for which a license may be revoked under section 186 of the Act. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

§ 19.31 Application for exemptions.

The Commission may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not result in undue hazard to life or property.

§ 19.32 Discrimination prohibited.

No person shall on the ground of sex be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity licensed by the Nuclear Regulatory Commission. This provision will be enforced through agency provisions and rules similar to those already established, with respect to racial and other discrimination, under title VI of the Civil Rights Act of 1964. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

§ 19.20 Employee protection.

Employment discrimination by a licensee or a contractor or subcontractor of a licensee against an employee for engaging in protected activities under this part or Parts 30, 40, 50, 60, 70, 72, or 150 of this chapter is prohibited.

38 FR 22217

40 FR 8774

38 FR 22217

40 FR 8774

47 FR 30452

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS - ENERGY

§ 20.1

**PART
20**

STANDARDS FOR PROTECTION AGAINST RADIATION

§ 20.3(a)

**PART 20—STANDARDS FOR
PROTECTION AGAINST RADIATION**

GENERAL PROVISIONS

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Authority: Secs. 53, 63, 66, 81, 103, 104, 161, 88 Stat. 930, 933, 935, 936, 937, 948, as amended; (42 U.S.C. 2073, 2083, 2095, 2111, 2133, 2154, 2201) sec. 201, as amended, 202, 208, Pub. L. 90-436, 88 Stat. 1242, 1244, 1246, Pub. L. 94-79, 88 Stat. 413 (42 U.S.C. 8041, 8042, 8046).

For the purposes of sec. 223, 88 Stat. 954, as amended, (42 U.S.C. 2273), §§ 20.101, 20.102, 20.103(a) (b), and (f), 20.104 (a) and (b), 20.105(b), 20.106(a), 20.301, 20.202(a), 20.206, 20.207, 20.301, 20.303, 20.304 and 20.305 are issued under sec. 161b, 88 Stat. 948, as amended, (42 U.S.C. 2201(b)); and §§ 20.102, 20.103(e), 20.401-20.407, 20.408(b) and 20.409 are issued under sec. 161c, 88 Stat. 950, as amended, (42 U.S.C. 2201(c)).

GENERAL PROVISIONS

§ 20.1 Purpose.
(a) The regulations in this part establish standards for protection against radiation hazards arising out of activities under licenses issued by the Nuclear Regulatory Commission and are issued pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974.

(b) The use of radioactive material or other sources of radiation not licensed by the Commission is not subject to the regulations in this part. However, it is the purpose of the regulations in this part to control the possession, use, and transfer of licensed material by any licensee in such a manner that the total dose to an individual (including exposures to licensed and unlicensed radioactive material and to other unlicensed sources of radiation, whether in the possession of the licensee or any other person, but not including exposures to radiation from natural background sources or medical diagnosis and therapy) does not exceed the standards of radiation protection prescribed in the regulations in this part.

(c) In accordance with recommendations of the Federal Radiation Council, approved by the President, persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974

should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable. The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest.

§ 20.2 Scope.

The regulations in this part apply to all persons who receive, possess, use, or transfer material licensed pursuant to the regulations in Parts 30 through 35, 40, 60, 61, 70, or 72 of this chapter, including persons licensed to operate a production or utilization facility pursuant to Part 50 of this chapter and persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter.

§ 20.3

§ 20.3 Definitions.

(a) As used in this part:
(1) "Act" means the Atomic Energy Act of 1954 (68 Stat. 919) including any amendments thereto;
(2) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors, or gases;
(3) "Byproduct material" means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(4) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be such that no day is included in more than one calendar quarter or omitted from inclusion within a calendar quarter. No licensee shall change the method observed by him of determining calendar quarters except at the beginning of a calendar year.

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(5) "Commission" means the Nuclear Regulatory Commission or its duly authorized representatives;

(6) "Government agency" means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government;

(7) "Individual" means any human being;

(8) "Licensed material" means source material, special nuclear material, or by-product material received, possessed, used, or transferred under a general or specific license issued by the Commission pursuant to the regulations in this chapter;

(9) "License" means a license issued under the regulations in Parts 30 through 35.40, 60, 61, 70 or 72 of this chapter. "Licensee" means the holder of such license;

(10) "Occupational dose" includes exposure of an individual to radiation (i) in a restricted area; or (ii) in the course of employment in which the individual's duties involve exposure to radiation, provided, that "occupational dose" shall not be deemed to include any exposure of an individual to radiation for the purpose of medical diagnosis or medical therapy of such individual.

(11) "Person" means: (i) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department (except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244)), any State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (ii) any legal successor, representative, agent, or agency of the foregoing.

(12) "Radiation" means any or all of the following: alpha rays, beta rays, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other atomic particles; but not sound or radio waves, or visible, infrared, or ultraviolet light;

(13) "Radioactive material" includes any such material whether or not subject to licensing control by the Commission;

(14) "Restricted area" means any area access to which is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. "Restricted area" shall not include any areas used as residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area;

(15) "Source material" means: (i) Uranium or thorium, or any combination thereof, in any physical or chemical form; or (ii) ores which contain by weight one-twentieth of one percent (0.05%) or more of (a) uranium, (b) thorium or (c) any combination thereof. Source material does not include special nuclear material.

(16) "Special nuclear material" means: (i) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the act, determines to be special nuclear material; but does not include source material; or (ii) any material artificially enriched by any of the foregoing but does not include source material;

(17) "Unrestricted area" means any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials, and any area used for residential quarters.

(18) "Department" means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233

at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

(19) "Termination" means the end of employment with the licensee or, in the case of individuals not employed by the licensee, the end of a work assignment in the licensee's restricted areas in a given calendar quarter, without expectation or specific scheduling of reentry into the licensee's restricted areas during the remainder of that calendar quarter.

(b) Definitions of certain other words and phrases as used in this part are set forth in other sections, including:

- (1) "Airborne radioactivity area" defined in § 20.203;
- (2) "Radiation area" and "high radiation area" defined in § 20.202;
- (3) "Personnel monitoring equipment" defined in § 20.202;
- (4) "Survey" defined in § 20.201;
- (5) Units of measurement of dose (rad, rem) defined in § 20.4;
- (6) Units of measurement of radioactivity defined in § 20.5.

§ 20.4 Units of radiation dose.

(a) "Dose," as used in this part, is the quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body. When the regulations in this part specify a dose during a period of time, the dose means the total quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body during such period of time. Several different units of dose are in current use. Definitions of units as used in this part are set forth in paragraphs (b) and (c) of this section.

(b) The rad, as used in this part, is a measure of the dose of any ionizing radiation to body tissues in terms of the energy absorbed per unit mass of the tissue. One rad is the dose corresponding to the absorption of 100 ergs per gram of tissue. (One millirad (mrad)=0.001 rad.)

(c) The rem, as used in this part, is a measure of the dose of any ionizing radiation to body tissues in terms of its estimated biological effect relative to a dose of one roentgen (r) of X-rays. (One millirem (mrem)=0.001 rem.) The relation of the rem to other dose units depends upon the biological effect under consideration and upon the conditions of irradiation. For the purpose of the regulations in this part, any of the following is considered to be equivalent to a dose of one rem:

- (1) A dose of 1 r due to X- or gamma radiation;
- (2) A dose of 1 rad due to X-, gamma, or beta radiation;

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(3) A dose of 0.1 rad due to neutrons or high energy protons;

(4) A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye; If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron dose in rads, as provided in paragraph (c)(3) of this section, one rem of neutron radiation may, for purposes of the regulations in this part, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

NEUTRON FLUX DOSE EQUIVALENTS

Neutron energy (Mev)	Number of neutrons per square centimeter equivalent to a dose of 1 rem (neutrons/cm ²)	Average flux to deliver 100 millirem in 40 hours (neutrons/cm ² sec.)
Thermal	970×10^4	670
0.001	720×10^4	500
0.005	620×10^4	570
0.02	400×10^4	280
0.1	120×10^4	80
0.5	43×10^4	30
1.0	26×10^4	16
2.5	29×10^4	20
5.0	26×10^4	18
7.5	24×10^4	17
10	24×10^4	17
10 to 30	14×10^4	10

(d) For determining exposures to X or gamma rays up to 3 Mev, the dose limits specified in §§ 20.101 to 20.104, inclusive, may be assumed to be equivalent to the "air dose". For the purpose of this part "air dose" means that the dose is measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of highest dosage rate.

§ 20.5 Units of radioactivity.

(a) Radioactivity is commonly, and for purposes of the regulations in this part shall be, measured in terms of disintegrations per unit time or in curies.

One curie = 3.7×10^{10} disintegrations per second (dps) = 2.2×10^{13} disintegrations per minute (dpm). Commonly used submultiples of the curie are the millicurie and the microcurie:

- (1) One millicurie (mCi) = 0.001 curie (Ci) = 3.7×10^7 dps.
- (2) One microcurie (μ Ci) = 0.000001 curie = 3.7×10^4 dps.

(b) [Deleted 40 FR 50704.]

(c) [Deleted 39 FR 23990.]

§ 20.6 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 20.7 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Communications, reports, and applications may be delivered in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; or at 7920 Norfolk Avenue, Bethesda, Maryland.

§ 20.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0014.

(b) The approved information collection requirements contained in this part appear in §§ 20.102, 20.103, 20.106, 20.108, 20.203, 20.205, 20.302, 20.311, 20.401, 20.402, 20.403, 20.405, 20.407, 20.408, and 20.409.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

- (1) In §§ 20.101 and 20.102, Form NRC-4 is approved under control number 3150-0005.
- (2) In § 20.401, Form NRC-6 is approved under control number 3150-0008.

PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS

§ 20.101 Radiation dose standards for individuals in restricted areas.

(a) In accordance with the provisions of § 20.102(a), and except as provided in paragraph (b) of this section, no licensee shall possess, use, or transfer licensed material in such a manner as to

cause any individual in a restricted area to receive in any period of one calendar quarter from radioactive material and other sources of radiation a total occupational dose in excess of the standards specified in the following table:

REMS PER CALENDAR QUARTER

1. Whole body, head and trunk, active blood-forming organs, lens of eyes, or gonads	1 1/4
2. Hands and forearms, feet and ankles	18%
3. Skin of whole body	7%

(b) A licensee may permit an individual in a restricted area to receive a total occupational dose to the whole body greater than that permitted under paragraph (a) of this section, provided:

(1) During any calendar quarter the total occupational dose to the whole body shall not exceed 3 rems; and

(2) The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5 (N-18) rems where "N" equals the individual's age in years at his last birthday; and

(3) The licensee has determined the individual's accumulated occupational dose to the whole body on Form NRC-4, or on a clear and legible record containing all the information required in that form; and has otherwise complied with the requirements of § 20.102. As used in paragraph (b), "Dose to the whole body" shall be deemed to include any dose to the whole body, gonads, active blood-forming organs, head and trunk, or lens of eye.

§ 20.102 Determination of prior dose.

(a) Each licensee shall require any individual, prior to first entry of the individual into the licensee's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of one calendar quarter an occupational dose in excess of 25 percent of the applicable standards specified in § 20.101(a) and § 20.104(a), to disclose in a written, signed statement, either: (1) That the individual had no prior occupational dose during the current calendar quarter, or (2) the nature and amount of any occupational dose which the individual may have received during that specifically identified current calendar quarter from sources of radiation possessed or controlled by other persons. Each licensee shall maintain records of such statements until the Commission authorizes their disposition.

(b) Before permitting, pursuant to § 20.101(b), any individual in a restricted area to receive an occupational radiation dose in excess of the standards specified in § 20.101(a), each licensee shall:

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(1) Obtain a certificate on Form NRC-4, or on a clear and legible record containing all the information required in that form, signed by the individual showing each period of time after the individual attained the age of 18 in which the individual received an occupational dose of radiation; and

(2) Calculate on Form NRC-4 in accordance with the instructions appearing therein, or on a clear and legible record containing all the information required in that form, the previously accumulated occupational dose received by the individual and the additional dose allowed for that individual under § 20.101(b).

(c)(1) In the preparation of Form NRC-4, or a clear and legible record containing all the information required in that form, the licensee shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the licensee obtains

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such reports, the licensee shall use the dose shown in the report in preparing the form. In any case where a licensee is unable to obtain reports of the individual's occupational dose for a previous complete calendar quarter, it shall be assumed that the individual has received the occupational dose specified in whichever of the following columns apply:

Part of body	Column 1— Assumed exposure in rems for calendar quarters prior to Jan. 1, 1961	Column 2— Assumed exposure in rems for calendar quarters beginning on or after Jan. 1, 1961
Whole body gonads, active blood-forming organs, head and trunk, lens of eye	3%	1%

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25 FR 0914

(2) The licensee shall retain and preserve records used in preparing Form NRC-4 until the Commission authorizes their disposition.

If calculation of the individual's accumulated occupational dose for all periods prior to January 1, 1961 yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in paragraph (b) of § 20.101, the excess may be disregarded.

§ 20.103 Exposure of individuals to concentrations of radioactive materials in air in restricted areas.

(a)(1) No licensee shall possess, use, or transfer licensed material in such a manner as to permit any individual in a restricted area to inhale a quantity of radioactive material in any period of one calendar quarter greater than the quantity which would result from inhalation for 40 hours per week for 13 weeks at uniform concentrations of radioactive material in air specified in Appendix B, Table I, Column 1.^{1,2} If

the radioactive material is of such form that intake by absorption through the skin is likely, individual exposures to radioactive material shall be controlled so that the uptake of radioactive material by any organ from either inhalation or absorption or both routes of intake³ in any calendar quarter does not exceed that which would result from inhaling such radioactive material for 40 hours per week for 13 weeks at uniform concentrations specified in Appendix B, Table I, Column 1.

(2) No licensee shall possess, use, or transfer mixtures of U-234, U-235, and U-238 in soluble form in such a

manner as to permit any individual in a restricted area to inhale a quantity of such material in excess of the intake limits specified in Appendix B, Table I, Column 1 of this part. If such soluble uranium is of a form such that absorption through the skin is likely, individual exposures to such material shall be controlled so that the uptake of such material by any organ from

either inhalation or absorption or both routes of intake⁴ does not exceed that which would result from inhaling such material at the limits specified in Appendix B, Table I, Column 1 and footnote 4 thereto.

(3) For purposes of determining compliance with the requirements of this section the licensee shall use suitable measurements of concentrations of radioactive materials in air for detecting and evaluating airborne radioactivity in restricted areas and in addition, as appropriate, shall use measurements of radioactivity in the body, measurements of radioactivity excreted from the body, or any combination of such measurements as may be necessary for timely detection and assessment of individual intakes of radioactivity by exposed individuals. It is assumed that an individual inhales radioactive material at the airborne concentration in which he is present unless he uses respiratory protective equipment pursuant to paragraph (c) of this section. When assessment of a particular individual's intake of radioactive material is necessary, intakes less than those which would result from inhalation for 2 hours in any one day or for 10 hours in any one week at uniform concentrations specified in Appendix B, Table I, Column 1 need not be included in such assessment, provided that for any assessment in excess of these amounts the entire amount is included.

(b)(1) The licensee shall, as a precautionary procedure, use process or other engineering controls, to the extent practicable, to limit concentrations of radioactive materials in air to levels below those which delimit an airborne radioactivity area as defined in § 20.203(d)(1)(ii).

(2) When it is impracticable to apply process or other engineering controls to limit concentrations of radioactive material in air below those defined in § 20.203(d)(1)(ii), other precautionary procedures, such as increased surveillance, limitation of working times, or provision of respiratory protective equipment, shall be used to maintain intake of radioactive material by any individual within any period of seven consecutive days as far below that intake of radioactive material which

would result from inhalation of such material for 40 hours at the uniform concentrations specified in Appendix B, Table I, Column 1 as is reasonably achievable. Whenever the intake of radioactive material by any individual exceeds this 40-hour control measure, the licensee shall make such evaluations and take such actions as are necessary to assure against recurrence. The licensee shall maintain records of such occurrences, evaluations, and actions taken in a clear and readily identifiable form suitable for summary review and evaluation.

(c) When respiratory protective equipment is used to limit the inhalation of airborne radioactive material pursuant to paragraph (b)(2) of this section, the licensee shall use equipment that is certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA). The licensee may make allowance for this use of respiratory protective equipment in estimating exposures of individuals to this material provided that:

¹Since the concentration specified for tritium oxide vapor assumes equal intakes by skin absorption and inhalation, the total intake permitted is twice that which would result from inhalation alone at the concentration specified for H 3 S in Appendix B, Table I, Column 1 for 40 hours per week for 13 weeks.

²For radon-222, the limiting quantity is that inhaled in a period of one calendar year. For radioactive materials designated "Sub" in the "Isotope" column of the table, the concentration value specified is based upon exposure to the material as an external radiation source. Individual exposures to these materials may be accounted for as part of the limitation on individual dose in § 20.101. These nuclides shall be subject to the precautionary procedures required by § 20.103(b)(1).

³Multiply the concentration values specified in Appendix B, Table I, Column 1, by 6.3×10^4 ml to obtain the quarterly quantity limit. Multiply the concentration value specified in Appendix B, Table I, Column 1, by 2.5×10^4 ml to obtain the annual quantity limit for Rn-222.

⁴Significant intake by ingestion or injection is presumed to occur only as a result of circumstances such as accident, inadvertence, poor procedure, or similar special conditions. Such intakes must be evaluated and accounted for by techniques and procedures as may be appropriate to the circumstances of the occurrence. Exposures so evaluated shall be included in determining whether the limitation on individual exposures in § 20.103(a)(1) has been exceeded.

⁵Regulatory guidance on assessment of individual intakes of radioactive material is given in Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program," single copies of which are available from the Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, upon written request.

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41 FR 27270

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(1) The licensee selects respiratory protective equipment that provides a protection factor greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 1 of this part. The equipment so selected shall be used so that the average concentration of radioactive material in the air that is inhaled during any period of uninterrupted use in an airborne radioactivity area, on any day, by any individual using the equipment, does not exceed the values specified in Appendix B, Table I, Column 1 of this part. For the purposes of this paragraph, the concentration of radioactive material in the air that is inhaled when respirators are worn may be estimated by dividing the ambient concentration in air by the protection factor specified in Appendix A of this part. If the exposure is later found to be greater than estimated, the corrected value shall be used; if the exposure is later found to be less than estimated, the corrected value may be used.

(2) The licensee maintains and implements a respiratory protection program that includes, as a minimum: air sampling sufficient to identify the hazard, permit proper equipment selection and estimate exposures; surveys and bioassays as appropriate to evaluate actual exposures; written procedures regarding selection, fitting, and maintenance of respirators, and testing of respirators for operability immediately prior to each use; written procedures regarding supervision and training of personnel and issuance records; and determination by a physician prior to initial use of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protective equipment.

(3) A written policy statement on respirator usage shall be issued covering such things as: use of practicable engineering controls instead of respirators; routine, nonroutine, and emergency use of respirators; and periods of respirator use and relief from respirator use. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other condition that might require such relief.

(4) The licensee uses equipment within limitations for type and mode of use and provides proper visual, communication, and other special capabilities (such as adequate skin protection) when needed.

(d) Unless otherwise authorized by the Commission, the licensee shall not assign protection factors in excess of

those specified in Appendix A of this part in selecting and using respiratory protective equipment. The Commission may authorize a licensee to use higher protection factors on receipt of an application (1) describing the situation for which a need exists for higher protection factors, and (2) demonstrating that the respiratory protective equipment will provide these higher protection factors under the proposed conditions of use.

(e) Where equipment of a particular type has not been tested and certified, or had certification extended, by NIOSH/MSHA, or where there is no existing schedule for test and certification of certain equipment, the licensee shall not make allowance for this equipment without specific authorization by the Commission. An application for this authorization must include a demonstration by testing, or on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(f) Only equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA shall be used as emergency devices.

(g) The licensee shall notify in writing the Director of the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix D at least 30 days before the date that respiratory protective equipment is first used under the provisions of this section.

§ 20.104 Exposure of minors.

(a) No licensee shall possess, use, or transfer licensed material in such a manner as to cause any individual within a restricted area who is under 18 years of age, to receive in any period of one calendar quarter from radioactive material and other sources of radiation in the licensee's possession a dose in excess of 10 percent of the limits specified in the table in paragraph (a) of § 20.101.

(b) No licensee shall possess, use or transfer licensed material in such a manner as to cause any individual within a restricted area, who is under 18 years of age to be exposed to airborne radioactive material possessed by the licensee in an average concentration in excess of the limits specified in Appendix B, Table II of this part. For purposes of this paragraph, concentrations may be averaged over periods not greater than a week.

(c) The provisions of §§ 20.103(b)(2) and 20.103(c) shall apply to exposures subject to paragraph (b). If this section except that the references in §§ 20.103(b)(2) and 20.103(c) to Appendix B, Table I, Column 1 shall be deemed to be references to Appendix B, Table II, Column 1.

§ 20.105 Permissible levels of radiation in unrestricted areas.

(a) There may be included in any application for a license or for amendment of a license proposed limits upon levels of radiation in unrestricted areas resulting from the applicant's possession or use of radioactive material and other sources of radiation. Such applications should include information as to anticipated average radiation levels and anticipated occupancy times for each unrestricted area involved. The Commission will approve the proposed limits if the applicant demonstrates that the proposed limits are not likely to cause any individual to receive a dose to the whole body in any period of one calendar year in excess of 0.5 rem.

(b) Except as authorized by the Commission pursuant to paragraph (a) of this section, no licensee shall possess, use or transfer licensed material in such a manner as to create in any unrestricted area from radioactive material and other sources of radiation in his possession:

(1) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of two millirems in any one hour, or

(2) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 100 millirems in any seven consecutive days.

(c) In addition to other requirements of this part, licensees engaged in uranium fuel cycle operations subject to the provisions of 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," shall comply with that part.

§ 20.106 Radioactivity in effluents to unrestricted areas.

(a) A licensee shall not possess, use, or transfer licensed material so as to release to an unrestricted area radioactive material in concentrations which exceed the limits specified in Appendix B, Table II of this part, except as authorized pursuant to § 20.302 or paragraph (b) of this section. For purposes of this section concentrations may be averaged over a period not greater than one year.

(b) An application for a license or amendment may include proposed limits higher than those specified in paragraph (a) of this section. The

Commission will approve the proposed limits if the applicant demonstrates:

(1) That the applicant has made a reasonable effort to minimize the radioactivity contained in effluents to unrestricted areas; and

(2) That it is not likely that radioactive material discharged in the effluent would result in the exposure of an individual to concentrations of radioactive material in air or water exceeding the limits specified in Appendix B, Table II of this part.

(c) An application for higher limits pursuant to paragraph (b) of this section shall include information demonstrating that the applicant has made a reasonable effort to minimize the radioactivity discharged in effluents to unrestricted areas, and shall include, as pertinent:

(1) Information as to flow rates, total volume of effluent, peak concentration of each radionuclide in the effluent, and concentration of each radionuclide in the effluent averaged over a period of one year at the point where the effluent leaves a stack, tube, pipe, or similar conduit;

(2) A description of the properties of the effluents, including:

(i) Chemical composition;

(ii) Physical characteristics, including suspended solids content in liquid effluents, and nature of gas or aerosol for air effluents;

(iii) The hydrogen ion concentrations (pH) of liquid effluents; and

(iv) The size range of particulates in effluents released into air.

(3) A description of the anticipated human occupancy in the unrestricted area where the highest concentration of radioactive material from the effluent is expected, and, in the case of a river or stream, a description of water uses downstream from the point of release of the effluent.

(4) Information as to the highest concentration of each radionuclide in an unrestricted area, including anticipated concentrations averaged over a period of one year:

(i) In air at any point of human occupancy; or

(ii) In water at points of use downstream from the point of release of the effluent.

(5) The background concentration of radionuclides in the receiving river or stream prior to the release of liquid effluent.

(6) A description of the environmental monitoring equipment, including sensitivity of the system, and procedures and calculations to determine concentrations of radionuclides in the unrestricted area and possible recon-

centrations of radionuclides.

(7) A description of the waste treatment facilities and procedures used to reduce the concentration of radionuclides in effluents prior to their release.

(d) For the purposes of this section the concentration limits in Appendix B, Table II of this part shall apply at the boundary of the restricted area. The concentration of radioactive material discharged through a stack, pipe or similar conduit may be determined with respect to the point where the material leaves the conduit. If the conduit discharges within the restricted area, the concentration at the boundary may be determined by applying appropriate factors for dilution, dispersion, or decay between the point of discharge and the boundary.

(e) In addition to limiting concentrations in effluent streams, the Commission may limit quantities of radioactive materials released in air or water during a specified period of time if it appears that the daily intake of radioactive material from air, water, or food by a suitable sample of an exposed population group, averaged over a period not exceeding one year, would otherwise exceed the daily intake resulting from continuous exposure to air or water containing one-third the concentration of radioactive materials specified in Appendix B, Table II of this part.

(f) The provisions of paragraphs (a) through (e) of this section do not apply to disposal of radioactive material into sanitary sewerage systems, which is governed by § 20.303.

(g) In addition to other requirements of this part, licensees engaged in uranium fuel cycle operations subject to the provisions of 40 CFR Part 190, "Environmental Radiation Protection Standard for Nuclear Power Operations," shall comply with that part.

§ 20.107 Medical diagnosis and therapy.

Nothing in the regulations in this part shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical therapy.

§ 20.108 Orders requiring furnishing of bio-assay services.

Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the Commission may incorporate appropriate provisions in any license, directing the licensee to make available to the individual appropriate bio-assay services and to furnish a copy of the reports of such services to the Commission.

PRECAUTIONARY PROCEDURES

§ 20.201 Surveys.

(a) As used in the regulations in this part, "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present.

(b) Each licensee shall make or cause to be made such surveys as (1) may be necessary for the licensee to comply with the regulations in this part, and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present.

§ 20.202 Personnel monitoring.

(a) Each licensee shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by:

(1) Each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in paragraph (a) of § 20.101.

(2) Each individual under 18 years of age who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 5 percent of the applicable value specified in paragraph (a) of § 20.101.

(3) Each individual who enters a high radiation area.

(b) As used in this part,

(1) "Personnel monitoring equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received (e.g., film badges, pocket chambers, pocket dosimeters, film rings, etc.);

(2) "Radiation area" means any area, accessible to personnel, in which there exists radiation, originating in whole or in part within licensed material, at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 millirem, or in any 5 consecutive days a dose in excess of 100 millirems;

(3) "High radiation area" means any area, accessible to personnel, in which there exists radiation originating in whole or in part within licensed material at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.

25 FR 10914

46 FR 18225

25 FR 10914

25 FR 14431

25 FR 14431

46 FR 18225

25 FR 10914

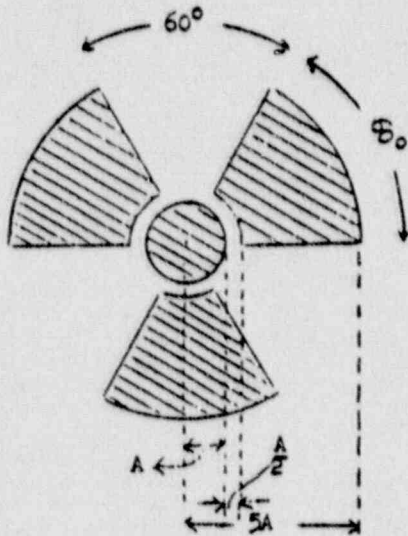
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§ 20.203 Caution signs, labels, signals and controls.

(a) *General.* (1) Except as otherwise authorized by the Commission, symbols prescribed by this section shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed by this section is the conventional three-bladed design:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta or purple.
2. Background is to be yellow.



(2) In addition to the contents of signs and labels prescribed in this section, licensees may provide on or near such signs and labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation or to radioactive material.

(b) *Radiation areas.* Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION

RADIATION AREA

(c) *High radiation areas.* (1) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION

HIGH RADIATION AREA

¹Or "Danger".

(2) Each entrance or access point to a high radiation area shall be:

(i) Equipped with a control device which shall cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in 1 hour upon entry into the area; or

(ii) Equipped with a control device which shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering the high radiation area and the licensee or a supervisor of the activity are made aware of the entry; or

(iii) Maintained locked except during periods when access to the area is required, with positive control over each individual entry.

(3) The controls required by paragraph (c)(2) of this section shall be established in such a way that no individual will be prevented from leaving a high radiation area.

(4) In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by paragraph (c)(2) of this section.

(5) Any licensee, or applicant for a license, may apply to the Commission for approval of methods not included in paragraphs (c)(2) and (4) of this section for controlling access to high radiation areas. The Commission will approve the proposed alternatives if the licensee or applicant demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area, and that the requirement of paragraph (c)(3) of this section is met.

(6) Each area in which there may exist radiation levels in excess of 500 rems in one hour at one meter from a sealed radio-active source¹ that is used to irradiate materials shall:

(i) Have each entrance or access point equipped with entry control devices which shall function automatically to prevent any individual from inadvertently entering the area when such radiation levels exist; permit deliberate entry into the area only after a control device is actuated that shall cause the radiation level within the area, from the sealed source, to be reduced below that at which it would be possible for an individual to receive a dose in excess of 100 mrem in one hour; and prevent operation of the source if the source would produce radiation levels in the area that could result in a dose to an individual in excess of 100 mrem in one hour. The entry control devices required by this paragraph (c)(6) shall be established in such a way that no individual will be prevented from leaving the area.

(ii) Be equipped with additional control devices such that upon failure of the entry control devices to function as required by paragraph (c)(6)(i) of this section the radiation level within the area, from the sealed source, shall be reduced below that at which it would be possible for an individual to receive a dose in excess of 100 mrem in one hour; and visible and audible alarm signals shall be generated to make an individual attempting to enter the area aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of such failure of the entry control devices.

(iii) Be equipped with control devices such that upon failure or removal of physical radiation barriers other than the source's shielded storage container the radiation level from the source shall be reduced below that at which it would be possible for an individual to receive a dose in excess of 100 mrem in one hour; and visible and audible alarm signals shall be generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier. When the shield for the stored source is a liquid, means shall be provided to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding. Physical radiation barriers that com-

¹This paragraph (c)(6) does not apply to radioactive sources that are used in teletherapy, in radiography, or in completely self-shielded irradiators in which the source is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual. This paragraph (c)(6) also does not apply to sources from which the radiation is incidental to some other use nor to nuclear reactor generated radiation other than radiation from byproduct, source, or special nuclear materials that are used in sealed sources in non-self-shielded irradiators.

²These requirements apply after Mar. 14, 1978. Each person licensed to conduct activities to which this paragraph (c)(6) applies and who is not in compliance with the provisions of this paragraph on Mar. 14, 1978, shall file with the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, on or before June 14, 1978, information describing in detail the actions taken or to be taken to achieve compliance with this paragraph by Dec. 14, 1978, and may continue activities in conformance with present license conditions and the provisions of the previously effective § 20.2034 until such compliance is achieved. For such persons compliance must be achieved not later than Dec. 14, 1978.

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prise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of this paragraph (c)(6)(iii).

(iv) Be equipped with devices that will automatically generate visible and audible alarm signals to alert personnel in the area before the source can be put into operation and in sufficient time for any individual in the area to operate a clearly identified control device which shall be installed in the area and which can prevent the source from being put into operation.

(v) Be controlled by use of such administrative procedure and such devices as are necessary to assure that the area is cleared of personnel prior to each use of the source preceding which use it might have been possible for an individual to have entered the area.

(vi) Be checked by a physical radiation measurement to assure that prior to the first individual's entry into the area after any use of the source, the radiation level from the source in the area is below that at which it would be possible for an individual to receive a dose in excess of 100 mrem in one hour.

(vii) Have entry control devices required in paragraph (c)(6)(i) of this section which have been tested for proper functioning prior to initial operation with such source of radiation on any day that operations are not uninterruptedly continued from the previous day or before resuming operations after any unintended interruption, and for which records are kept of the dates, times, and results of such tests of function. No operations other than those necessary to place the source in safe condition or to effect repairs on controls shall be conducted with such source unless control devices are functioning properly. The licensee shall submit an acceptable schedule for more complete periodic tests of the entry control and warning systems to be established and adhered to as a condition of the license.

(viii) Have those entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through such portals. Exit portals for processed materials shall be equipped to detect and signal the presence of loose radiation sources that are carried toward such an exit and to automatically prevent such loose sources from being carried out of the area.

(7) Licensees with, or applicants for, licenses for radiation sources that are within the purview of paragraph (c)(6) of this section, and that must be used in a variety of positions or in peculiar locations, such as open fields or forests, that make it impracticable to comply with certain requirements of paragraph (c)(6) of this section, such as those for the automatic control of radiation levels, may apply to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, for approval, prior to use of safety measures that are alternative to those specified in paragraph (c)(6) of this section, and that will provide at least an equivalent degree of personnel protection in the use of such sources. At least one of the alternative measures must include an entry-preventing interlock control based on a physical measurement of radiation that assures the absence of high radiation levels before an individual can gain access to an area where such sources are used.

(d) *Airborne radioactivity areas.* (1) As used in the regulations in this part "airborne radioactivity area" means (i) any room, enclosure, or operating area in which airborne radioactive materials composed wholly or partly of licensed material, exist in concentrations in excess of the amounts specified in Appendix B, Table I, Column 1 of this part; or (ii) any room, enclosure, or operating area in which airborne radioactive material composed wholly or partly of licensed material exists in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25 percent of the amounts specified in Appendix B Table I, Column 1 of this part.

(2) Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION¹

AIRBORNE RADIOACTIVITY AREA

(e) *Additional requirements.* (1) Each area or room in which licensed material is used or stored and which contains any radioactive material (other than natural uranium or thorium) in an amount exceeding 10 times the quantity of such material specified in Appendix C of this part shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

¹Or "Danger".

¹As appropriate, the information will include radiation levels, kinds of material, estimate of activity, date for which activity is estimated, mass enrichment, etc.

CAUTION¹

RADIOACTIVE MATERIAL(S)

(2) Each area or room in which natural uranium or thorium is used or stored in any amount exceeding one hundred times the quantity specified in Appendix C of this part shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION¹

RADIOACTIVE MATERIAL(S)

(f) *Containers.* (1) Except as provided in paragraph (f)(3) of this section, each container of licensed material shall bear a durable, clearly visible label identifying the radioactive contents.

(2) A label required pursuant to paragraph (f)(1) of this section shall bear the radiation caution symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". It shall also provide sufficient information² to permit individuals handling or using the containers, or working in the vicinity thereof, to take precautions to avoid or minimize exposures.

(3) Notwithstanding the provisions of paragraph (f)(1) of this section labeling is not required:

(i) For containers that do not contain licensed materials in quantities greater than the applicable quantities listed in Appendix C of this part.

(ii) For containers containing only natural uranium or thorium in quantities no greater than 10 times the applicable quantities listed in Appendix C of this part.

(iii) For containers that do not contain licensed materials in concentrations greater than the applicable concentrations listed in Appendix B, Table I, Column 2, of this part.

(iv) For containers when they are attended by an individual who takes the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established by the regulations in this part.

(v) For containers when they are in transport and packaged and labeled in accordance with regulations of the Department of Transportation.

(vi) For containers which are accessible³ only to individuals authorized to handle or use them, or to work in the vicinity thereof, provided that the contents are identified to such individuals by a readily available written record.

(vii) For manufacturing or process equipment, such as nuclear reactors, reactor components, piping, and tanks.

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(4) Each licensee shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

§ 20.204 Same: exceptions. Notwithstanding the provisions of § 20.203,

(a) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level twelve inches from the surface of the source container or housing does not exceed five millirem per hour.

(b) Rooms or other areas in hospitals are not required to be posted with caution signs, and control of entrance or access thereto pursuant to § 20.203(c) is not required, because of the presence of patients containing by-product material provided that there are personnel in attendance who will take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in the regulations in this part.

(c) Caution signs are not required to be posted at areas or rooms containing radioactive materials for periods of less than eight hours provided that (1) the materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established in the regulations in this part and; (2) such area or room is subject to the licensee's control.

(d) A room or other area is not required to be posted with a caution sign, and control is not required for each entrance or access point to a room or other area which is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with regulations of the Department of Transportation.

§ 20.205 Procedures for picking up, receiving, and opening packages.

(a)(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of the Type A quantities specified in paragraph (b) of this section shall:

(i) If the package is to be delivered to the licensee's facility by the carrier, make arrangements to receive the package when it is offered for delivery by the carrier; or

(ii) If the package is to be picked up by the licensee at the carrier's terminal, make arrangements to receive notification from the carrier of the arrival of the package, at the time of arrival.

(2) Each licensee who picks up a package of radioactive material from a carrier's terminal shall pick up the package expeditiously upon receipt of notification from the carrier of its arrival.

(b)(1) Each licensee, upon receipt of a package of radioactive material, shall monitor the external surfaces of the package for radioactive contamination caused by leakage of the radioactive contents, except:

(i) Packages containing no more than the exempt quantity specified in the table in this paragraph;

(ii) Packages containing no more than 10 millicuries of radioactive material consisting solely of tritium, carbon-14, sulfur-35, or iodine-125;

(iii) Packages containing only radioactive material as gases or in special form;

(iv) Packages containing only radioactive material in other than liquid form (including Mo-99/Tc-99m generators) and not exceeding the Type A quantity limit specified in the table in this paragraph; and

(v) Packages containing only radionuclides with half-lives of less than 30 days and a total quantity of no more than 100 millicuries.

The monitoring shall be performed as soon as practicable after receipt, but no later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours, or eighteen hours if received after normal working hours.

(2) If removable radioactive contamination in excess of 0.01 microcuries (22,000 disintegrations per minute) per 100 square centimeters of package surface is found on the external surfaces of the package, the licensee shall immediately notify the final delivering carrier and, by telephone and telegraph, mailgram or facsimile, the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office shown in Appendix D of this part.

TABLE OF EXEMPT AND TYPE A QUANTITIES

Table with 3 columns: Transport group, Exempt quantity limit (in millicuries), Type A quantity limit (in curies). Rows include I, II, III, IV, V, VI, VII, and Special Form.

The definitions of "transport group" and "special form" are specified in § 71.4 of this chapter.

[Footnote 1 removed 49 FR 19623]

(c)(1) Each licensee, upon receipt of a package containing quantities of radioactive material in excess of the Type A quantities specified in paragraph (b) of this section, other than those transported by exclusive use vehicle, shall monitor the radiation levels external to the package. The package shall be monitored as soon as practicable after receipt, but no later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours, or 18 hours if received after normal working hours.

(2) If radiation levels are found on the external surface of the package in excess of 200 millirem per hour, or at three feet from the external surface of the package in excess of 10 millirem per hour,

the licensee shall immediately notify by telephone and telegraph mailgram, or facsimile, the director of the appropriate NRC Regional Office listed in Appendix D, and the final delivering carrier.

(d) Each licensee shall establish and maintain procedures for safely opening packages in which licensed material is received, and shall assure that such procedures are followed and that due consideration is given to special instructions for the type of package being opened.

§ 20.206 Instruction of personnel.

Instructions required for individuals working in or frequenting any portion of a restricted area are specified in § 19.12 of this chapter.

§ 20.207 Storage and control of licensed materials in unrestricted areas.

(a) Licensed materials stored in an unrestricted area shall be secured from unauthorized removal from the place of storage.

(b) Licensed materials in an unrestricted area and not in storage shall be

For example, containers in locations such as water-filled canals, storage vaults, or hot cells.

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tended under the constant surveillance and immediate control of the licensee.

WASTE DISPOSAL

§ 20.301 General requirement.

No licensee shall dispose of licensed material except:

(a) By transfer to an authorized recipient as provided in the regulations in Parts 30, 40, 60, 61, 70 or 72 of this chapter, whichever may be applicable; or

(b) As authorized under § 20.302 or Part 61 of this chapter; or

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

§ 20.302 Method for obtaining approval of proposed disposal procedures.

(a) Any licensee or applicant for a license may apply to the Commission for approval of proposed procedures to dispose of licensed material in a manner not otherwise authorized in the regulations in this chapter. Each application should include a description of the licensed material and any other radioactive material involved, including the quantities and kinds of such material and the levels of radioactivity involved, and the proposed manner and conditions of disposal. The application should also include an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meteorological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures.

(b) The Commission will not approve any application for a license for disposal of licensed material at sea unless the applicant shows that sea disposal offers less harm to man or the environment than other practical alternative methods of disposal.

§ 20.303 Disposal by release into sanitary sewerage systems.

No licensee shall discharge licensed material into a sanitary sewerage system unless:

(a) It is readily soluble or dispersible in water; and

(b) The quantity of any licensed or other radioactive material released into the system by the licensee in any one day does not exceed the larger of paragraphs (b)(1) or (2) of this section.

(1) The quantity which, if diluted by the average daily quantity of sewage released into the sewer by the licensee, will result in an average concentration equal to the limits specified in Appendix B, Table I, Column 2 of this part; or

(2) Ten times the quantity of such material specified in Appendix C of this part; and

(c) The quantity of any licensed or other radioactive material released in any one month, if diluted by the average monthly quantity of water released by the licensee, will not result in an average concentration exceeding the limits specified in Appendix B, Table I, Column 2 of this part; and

(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.

§ 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.

§ 20.306 Disposal of specific wastes.

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

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

(b) 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.

(c) 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; and

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

§ 20.311 Transfer for disposal and manifests.

(a) Purpose. The requirements of this section are designed to control transfers of radioactive waste intended for disposal at a land disposal facility and establish a manifest tracking system and supplement existing requirements concerning transfers and recordkeeping for such wastes. The reporting and recordkeeping requirements contained in this section have been approved by the Office of Management and Budget; OMB approval No. 3150-0014.

(b) Each shipment of radioactive waste to a licensed land disposal facility must be accompanied by a shipment manifest that contains the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and EPA hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest must also indicate as completely as practicable: a physical description of the waste; the volume; radionuclide identity and quantity; the total radioactivity; and the principal chemical form. The solidification agent must be specified. Waste containing more than 0.1% chelating agents by weight must be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in § 61.55 of this chapter must be clearly identified as such in the manifest. The total quantity of the radionuclides H-3, C-14, Tc-99 and I-129 must be shown. The manifest required by this paragraph may be shipping papers used to meet Department of Transportation or

Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included. Copies of manifests required by this section may be legible carbon copies or legible photocopies.

(c) Each manifest must include a certification by the waste generator that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Commission. An authorized representative of the waste generator shall sign and date the manifest.

(d) Any generating licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs (d)(1) through (6) of this section. Any generating licensee who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of paragraphs (d)(4) through (6) of this section. A licensee shall:

(1) Prepare all wastes so that the waste is classified according to § 61.55 and meets the waste characteristics requirements in § 61.56 of this chapter;

(2) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with § 61.55 of this chapter;

(3) Conduct a quality control program to assure compliance with §§ 61.55 and 61.56 of this chapter; the program must include management evaluation of audits;

(4) Prepare shipping manifests to meet the requirements of §§ 20.311 (b) and (c) of this part;

(5) Forward a copy of the manifest to the intended recipient, at the time of shipment; or, deliver to a collector at the time the waste is collected, obtaining acknowledgement of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;

(6) Include one copy of the manifest with the shipment;

(7) Retain a copy of the manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by Parts 30, 40, and 70 of this chapter; and,

(8) For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with paragraph (h) of this section.

(e) Any waste collector licensee who handles only prepackaged waste shall:

(1) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;

(2) Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in paragraph (b) of this section. The collector licensee shall certify that nothing has been done to the waste which would invalidate the generator's certification;

(3) Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;

(4) Include the new manifest with the shipment to the disposal site;

(5) Retain a copy of the manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by Parts 30, 40, and 70 of this chapter, and retain information from generator manifests until disposition is authorized by the Commission; and,

(6) For any shipments or any part of a shipment for which acknowledgement of receipt is not received within the times set forth in this section, conduct an investigation in accordance with paragraph (h) of this section.

(f) Any licensed waste processor who treats or repackages wastes shall:

(1) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;

(2) Prepare a new manifest that meets the requirements of paragraphs (b) and (c) of this section. Preparation of the new manifest reflects that the processor is responsible for the waste;

(3) Prepare all wastes so that the waste is classified according to § 61.55 and meets the waste characteristics requirements in § 61.56 of this chapter;

(4) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with §§ 61.55 and 61.57 of this chapter;

(5) Conduct a quality control program to assure compliance with §§ 61.55 and 61.56 of this chapter. The program shall include management evaluation of audits;

(6) Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgement of receipt in the form of a signed copy of the manifest or

equivalent documentation by the collector;

(7) Include the new manifest with the shipment;

(8) Retain copies of original manifests and new manifests and documentation of acknowledgement of receipt as the record of transfer of licensed material required by Parts 30, 40, and 70 of this chapter; and

(9) For any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section, conduct an investigation in accordance with paragraph (h) of this section.

(g) The land disposal facility operator shall:

(1) Acknowledge receipt of the waste within one week of receipt by returning a signed copy of the manifest or equivalent documentation to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;

(2) Maintain copies of all completed manifests or equivalent documentation until the Commission authorizes their disposition; and

(3) Notify the shipper (i.e., the generator, the collector, or processor) and the Director of the nearest Commission Regional Office listed in Appendix D of this part when any shipment or part of a shipment has not arrived within 60 days after the advance manifest was received.

(h) Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section, must:

(1) Be investigated by the shipper if the shipper has not received notification of receipt within 20 days after transfer; and

(2) Be traced and reported. The investigation shall include tracing the shipment and filing a report with the nearest Commission Regional Office listed in Appendix D of this part. Each licensee who conducts a trace investigation shall file a written report with the nearest Commission's Regional office within 2 weeks of completion of the investigation.

47 FR 57446

47 FR 57446

47 FR 57446

§ 20.401 Records of surveys, radiation monitoring, and disposal.

(a) Each licensee shall maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under § 20.202 of the regulations in this part. Such records shall be kept on Form NRC-5, in accordance with the instructions contained in that form or on clear and legible records containing all the information required by Form NRC-5. The doses entered on the forms or records shall be for periods of time not exceeding one calendar quarter.

25 FR 10984

(b) Each licensee shall maintain records in the same units used in this part, showing the results of surveys required by § 20.201(b), monitoring required by §§ 20.205(b) and 20.205(c), and disposals made under §§ 20.302, 20.303, removed § 20.304,¹ and Part 61 of this chapter.

47 FR 57446

(c)(1) Records of individual exposure to radiation and to radioactive material which must be maintained pursuant to the provisions of paragraph (a) of this section and records of bioassays, including results of whole body counting examinations, made pursuant to § 20.108, shall be preserved until the Commission authorizes disposition.

(2) Records of the results of surveys and monitoring which must be maintained pursuant to paragraph (b) of this section shall be preserved for two years after completion of the survey except that the following records shall be maintained until the Commission authorizes their disposition: (i) Records of the results of surveys to determine compliance with § 20.103(a); (ii) in the absence of personnel monitoring data, records of the results of surveys to determine external radiation dose; and (iii) records of the results of surveys used to evaluate the release of radioactive effluents to the environment.

61 FR 18300

(3) Records of disposal of licensed materials made pursuant to §§ 20.302, 20.303, removed § 20.304, and Part 61 of this chapter are to be maintained until the Commission authorizes their disposition.

(4) Records which must be maintained pursuant to this part may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations.

(5) If there is a conflict between the Commission's regulations in this part, license condition, or technical specification, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part for such records shall apply unless the Commission pursuant to § 20.501, has granted a specific exemption from the record retention requirements specified in the regulations in this part.

§ 20.402 Reports of theft or loss of licensed material.

(a)(1) Each licensee shall report to the Commission, by telephone, immediately after it determines that a loss or theft of licensed material has occurred in such quantities and under such circumstances that it appears to the licensee that a substantial hazard may result to persons in unrestricted areas.

(2) Reports must be made as follows:

(i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center in accordance with § 50.72 of this chapter.

(ii) All other licensees shall make reports to the Administrator of the appropriate NRC Regional Office listed in Appendix D of this part.

(b) Each licensee who makes a report under paragraph (a) of this section shall, within 30 days after learning of the loss or theft, make a report in writing to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of this part. The report shall include the following information:

- (1) A description of the licensed material involved, including kind, quantity, chemical, and physical form;
- (2) A description of the circumstances under which the loss or theft occurred;
- (3) A statement of disposition or probable disposition of the licensed material involved;
- (4) Radiation exposures to individ-

uals, circumstances under which the exposures occurred, and the extent of possible hazard to persons in unrestricted areas;

(5) Actions which have been taken, or will be taken, to recover the material; and

(6) Procedures or measures which have been or will be adopted to prevent a recurrence of the loss or theft of licensed material.

(c) Subsequent to filing the written report the licensee shall also report any substantive additional information on the loss or theft which becomes available to the licensee, within 30 days after he learns of such information.

(d) Any report filed with the Commission pursuant to this section shall be so prepared that names of individuals who may have received exposure to radiation are stated in a separate part of the report.

(e) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported in accordance with the procedures described in § 50.73 (b), (c), (d), (e), and (g) of this chapter and must include the information required in paragraph (b) of this section. Events reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (b) of this section.

§ 20.403 Notifications of incidents.

(a) *Immediate notification.* Each licensee shall immediately report any events involving byproduct, source, or special nuclear material possessed by the licensee that may have caused or threatens to cause:

(1) Exposure of the whole body of any individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual of 150 rems or more of radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rems or more of radiation; or

(2) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limits specified for such materials in Appendix B, Table II of this part; or

(3) A loss of one working week or more of the operation of any facilities affected; or

(4) Damage to property in excess of \$200,000.

(b) *Twenty-four hour notification.* Each licensee shall within 24 hours of discovery of the event, report any event involving licensed material possessed by the licensee that may have caused or threatens to cause:

(1) Exposure of the whole body of any individual to 5 rems or more of radiation; exposure of the skin of the whole body of any individual to 30 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms to 75 rems or more of radiation; or

(2) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 500 times the limits specified for such materials in Appendix B, Table II of this part; or

(3) A loss of one day or more of the operation of any facilities affected; or

(4) Damage to property in excess of \$2,000.

(c) Any report filed with the Commission pursuant to this section shall be prepared so that names of individuals who have received exposure to radiation will be stated in a separate part of the report.

(d) Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees that have an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of this section to the NRC Operations Center in accordance with § 50.72 of this chapter.

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone and by telegram, mailgram, or facsimile to the Administrator of the appropriate NRC Regional Office listed in Appendix D of this part.

§ 20.404 (Reserved)

§ 20.405 Reports of overexposures and excessive levels and concentrations.

(a)(1) In addition to any notification required by § 20.403 of this part, each licensee shall make a report in writing concerning any one of the following types of incidents within 30 days of its occurrence:

(i) Each exposure of an individual to radiation in excess of the applicable limits in §§ 20.101 or 20.104(a) of this part, or the licensee;

(ii) Each exposure of an individual to radioactive material in excess of the applicable limits in §§ 20.103(a)(1), 20.103(a)(2), or 20.104(b) of this part, or in the licensee;

(iii) Levels of radiation or concentrations of radioactive material in a restricted area in excess of any other applicable limit in the license;

(iv) Any incident for which notification is required by § 20.403 of this part; or

(v) Levels of radiation or concentrations of radioactive material (whether or not involving excessive exposure of any individual) in an unrestricted area in excess of ten times any applicable limit set forth in this part or in the license.

(2) Each report required under paragraph (a)(1) of this section must describe the extent of exposure of individuals to radiation or to radioactive material, including:

(i) Estimates of each individual's exposure as required by paragraph (b) of this section;

(ii) Levels of radiation and concentrations of radioactive material involved;

(iii) The cause of the exposure, levels or concentrations; and

(iv) Corrective steps taken or planned to prevent a recurrence.

(b) Any report filed with the Commission pursuant to paragraph (a) of this section shall include for each individual exposed the name, social security number, and date of birth, and an estimate of the individual's exposure. The report shall be prepared so that this information is stated in a separate part of the report.

(c)(1) In addition to any notification required by § 20.403 of this part, each licensee shall make a report in writing of levels of radiation or releases of radioactive material in excess of limits specified by 40 CFR Part 190.

"Environmental Radiation Protection Standards for Nuclear Power Operations," or in excess of license conditions related to compliance with 40 CFR Part 190.

(2) Each report submitted under paragraph (c)(1) of this section must describe:

(i) The extent of exposure of individuals to radiation or to radioactive material;

(ii) Levels of radiation and concentrations of radioactive material involved;

(iii) The cause of the exposure, levels, or concentrations; and

(iv) Corrective steps taken or planned to assure against a recurrence, including the schedule for achieving conformance with 40 CFR Part 190 and with associated license conditions.

(d) For holders of an operating license for a nuclear power plant, the incidents included in paragraphs (a) or (c) of this section must be reported in accordance

with the procedures described in paragraphs 50.73 (b), (c), (d), (e), and (g) of this chapter and must also include the information required by paragraphs (a) and (c) of this section. Incidents reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraphs (a) or (c) of this section.

(e) All other licensees who make reports under paragraphs (a) or (c) of this section shall, within 30 days after learning of the overexposure or excessive level or concentration, make a report in writing to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of this part.

§ 20.406 (Reserved)

§ 20.407 Personnel monitoring reports.

Each person described in § 20.406 of this part shall, within the first quarter of each calendar year, submit to the Director, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, the reports specified in paragraphs (a) and (b) of this section, covering the preceding calendar year.¹

(a) A report of either (1) the total number of individuals for whom personnel monitoring was required under § 20.202(a) or § 34.33(a) of this chapter during the calendar year; or (2) the total number of individuals for whom personnel monitoring was provided during the calendar year: *Provided, however,* That such total includes at least the number of individuals required to be reported under paragraph (a)(1) of this section. The report shall indicate whether it is submitted in accordance with paragraph (a)(1) or (a)(2) of this section. If personnel monitoring was not required to be provided to any individual by the licensee under §§ 20.202(a) or 34.33(a) of this chapter during the calendar year, the licensee shall submit a negative report indicating that such personnel monitoring was not required.

(b) A statistical summary report of the personnel monitoring information recorded by the licensee for individuals for whom personnel monitoring was either required or provided, as described in paragraph (a) of this section, indicating the number of individuals whose total whole body exposure recorded during the previous calendar

¹ A licensee whose license expires or terminates prior to, or on the last day of the calendar year, shall submit reports at the expiration or termination of the license, covering that part of the year during which the license was in effect.

year was in each of the following estimated exposure ranges:

Estimated whole body exposure range (rems) ¹	Number of individuals in each range
No measurable exposure	
Measurable exposure less than 0.1	
0.1 to 0.25	
0.25 to 0.5	
0.5 to 0.75	
0.75 to 1	
1 to 2	
2 to 3	
3 to 4	
4 to 5	
5 to 6	
6 to 7	
7 to 8	
8 to 9	
9 to 10	
10 to 11	
11 to 12	
12+	

¹ Individual values exactly equal to the values separating exposure ranges shall be reported in the higher range.

The low exposure range data are required in order to obtain better information about the exposures actually recorded. This section does not require improved measurements.

§ 20.408 Reports of personnel monitoring on termination of employment or work.

(a) This section applies to each person licensed by the Commission to:

(1) Operate a nuclear reactor designed to produce electrical or heat energy pursuant to § 50.21(b) or § 50.22 of this chapter or a testing facility as defined in § 50.2 of this chapter.

(2) Possess or use byproduct material for purposes of radiography pursuant to Parts 30 and 34 of this chapter;

(3) Possess or use at any one time, for purposes of fuel processing, fabricating, or reprocessing, special nuclear material in a quantity exceeding 5,000 grams of contained uranium-235, uranium-233, or plutonium or any combination thereof pursuant to Part 70 of this chapter;

(4) Possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 of this chapter; or

(5) Possess spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter; or

(6) Possess or use at any one time, for processing or manufacturing for distribution pursuant to Parts 30, 32, or 33 of this Chapter, byproduct material in quantities exceeding any one of the following quantities:

Radionuclide ¹	Quantity in curies
Cesium-137	1
Cobalt-60	1
Gold-198	100
Iodine-131	1
Iridium-192	10
Krypton-85	1,000
Promethium-147	10
Technetium-99m	1,000

¹The Commission may require, as a license condition, or by rule, regulation or order pursuant to § 20.502, reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

§ 20.409 Notifications and reports to individuals.

(a) Requirements for notifications and reports to individuals of exposure to radiation or radioactive material are specified in § 19.13 of this chapter.

(b) When a licensee is required pursuant to §§ 20.405 or 20.408 to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Commission, and shall comply with the provisions of § 19.13(a) of this chapter.

(7) Receive radioactive waste from other persons for disposal under Part 61 of this chapter.

(b) When an individual terminates employment with a licensee described in paragraph (a) of this section, or an individual assigned to work in such a licensee's facility, but not employed by the licensee, completes the work assignment in the licensee's facility, the licensee shall furnish to the Director, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a report of the individual's exposures to radiation and radioactive material, incurred during the period of employment or work assignment in the licensee's facility, containing information recorded by the licensee pursuant to §§ 20.401(a) and 20.106. Such report shall be furnished within 30 days after the exposure of the individual has been determined by the licensee or 90 days after the date of termination of employment or work assignment, whichever is earlier.

EXCEPTIONS AND ADDITIONAL REQUIREMENTS

§ 20.501 Applications for exemptions.

The Commission may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not result in undue hazard to life or property.

§ 20.502 Additional requirements.

The Commission may, by rule, regulation, or order, impose upon any licensee such requirements, in addition to those established in the regulations in this part, as it deems appropriate or necessary to protect health or to minimize danger to life or property.

ENFORCEMENT

§ 20.601 Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Atomic Energy Act of 1954, as amended, or Title II of the Energy Reorganization Act of 1974, or any regulation or order issued thereunder. A court order may be obtained for the payment of a civil penalty imposed pursuant to section 234 of the Act for violation of section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act, or section 206 of the Energy Reorganization Act of 1974, or any rule, regulation, or order issued thereunder, or any term, condition, or limitation of any license issued thereunder, or for any violation for which a license may be revoked under section 186 of the Act. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

[Note removed 49 FR 19623]

PART 20 • STANDARDS FOR PROTECTION AGAINST RADIATION

APPENDIX A.—PROTECTION FACTORS FOR RESPIRATORS*

Description ¹	Model ¹	Protection factors ²		Tests and certifies equipment—National Institute for Occupational Safety and Health/Mines Safety and Health Administration tests for permissibility
		Particulates only	Particulates, gases and vapors ³	
I. Air-purifying respirators⁴				
Facepiece half-mask ⁵	RP	10		30 CFR Part 11, Subpart K
Facepiece full	RP	50		
Facepiece half-mask, full or hood	RP	1,000		
II. Atmosphere-supplying respirators				
1. Air-line respirator				
Facepiece half-mask	CP		1,000	30 CFR Part 11, Subpart J
Facepiece half-mask	D		5	
Facepiece full	CP		5,000	
Facepiece full	D		5	
Facepiece full	PC		5,000	
Head	CP		(f)	
Head	CP		(f)	
2. Self-contained breathing apparatus (SCBA)				
Facepiece full	D		50	30 CFR Part 11, Subpart H
Facepiece full	PC		50	
Facepiece full	PC		50	
Facepiece full	RP		1,000	30 CFR Part 11, § 11.63(b)
Facepiece full	RP		"	
III. Combination respirator: Any combination of air-purifying and atmosphere-supplying respirators.				

* For use in the selection of respiratory protective devices to be used only where the contaminants have been identified and the concentrations (or possible concentrations) are known.
¹ Only for shower faces and where resting respirators with the use of expiring hazardous against the skin. (Hoods and suits are exempt.)
² The model symbols are defined as follows: CP = continuous flow; D = demand; RP = negative pressure (i.e., negative pressure during inhalation); PC = pressure demand (i.e., always positive pressure); RP = positive pressure; RC = demand, restricting (closed circuit); RP = positive pressure, restricting (closed circuit).
³ The protection factor is a measure of the degree of protection offered by a respirator defined as the ratio of the concentration of airborne radioactive material outside the respiratory protective equipment to that inside the equipment (actual) under conditions of use. It is applied to the ambient airborne concentration to estimate the concentrations inhaled by the wearer according to the following formula:
 Concentration inhaled = Ambient airborne concentration / Protection factor

⁴ The protection factors apply.
⁵ Only for tested individuals wearing properly fitted respirators used and maintained under supervision in a well-planned respiratory protective program.
⁶ For air-purifying respirators only: must have high efficiency particulate filters (above 99.97% removal efficiency by normally generated 0.3 µm NaCl) (DOP) test are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards.
⁷ The minimum to be made for the use of certain against radioactive gases or vapors.
⁸ For atmosphere-supplying respirators only when supplied with adequate respiratory or respiratory or shall be provided of the quality and quantity required in accordance with NIOSH/MSHA certification (described in 30 CFR Part 11). Oxygen and or that not be used in the same apparatus.
⁹ Excluding radioactive contaminants that present an absorption or submersion hazard. For plutonium cases, approximately one half of the intake occurs by absorption through the skin so that an overall protection factor of less than 2 is appropriate when atmosphere-supplying respirators are used to protect against plutonium cases if the protection factor for a device is 5, the effective protection factor for plutonium cases is about 1.4, for devices with protection factors of 10 the effective protection factor for plutonium cases is about 1.7, and for devices with protection factors of 100 or more the effective factor for plutonium cases is about 1.8. Air-purifying respirators are not suitable for protection against plutonium cases. See also footnote 1 concerning supply-or suits.
¹⁰ Under-ohm test only. This type of respirator is not satisfactory for use where it might be possible (i.e., in an accident or emergency case to occur) for the ambient airborne concentration to reach instantaneous values greater than 10 times the pertinent values in Table 1, Column 1 of Appendix B of this part. This type of respirator is not suitable for protection against plutonium or other high-activity materials. The mask shall be tested for fit with various events, prior to use, each time it is donned.
¹¹ Equipment shall be certified in 5 minutes that provides that proper fit factors are maintained. A protection factor of no more than 1,000 may be used for tested and certified supplied air hoods when a minimum of 6 cubic feet per minute is maintained and calibrated spring pressure gauges or flow measuring devices are used. A protection factor of up to 2,000 may be used for tested and certified hoods only when the air flow is maintained at the manufacturer's recommended maximum rate for the equipment, this rate is greater than 6 cubic feet per minute, and calibrated spring pressure gauges or flow measuring devices are used.
¹² The design of the supplied-air hood or helmet (with a minimum flow of 6 cfm of air) may determine its overall efficiency and the protection it provides. For example, some hoods enclose the wearer's head and the breathing tube when the wearer works with hands-over-head. This design may be overcome if a short open-tube connection to the hood is worn under a cap or overalls. Other features specified by the approval agency shall be considered before using a hood in certain types of atmospheres, such as the design and its permeability to the environment under conditions of use.
¹³ Approved protection factors shall be determined from 20 CFR 109(e), taking into account the design of the suit and its permeability to the environment under conditions of use. There shall be a readily accessible person equipped with self-contained breathing apparatus and communications equipment whenever supplied-air suits are used.
¹⁴ No approval certificates are currently available for this equipment. Equipment shall be evaluated by testing or on the basis of reliable test information.
¹⁵ This type of respirator may provide greater protection and be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other exposures to external sources such as skin absorption shall be taken into account in these circumstances.
¹⁶ Qualitative fit testing shall be performed on each individual and no more than 0.02% leakage is allowed with the type of apparatus. Permissible outward leakage of gas from the fit or any negative pressure self-contained breathing apparatus is unacceptable because service life will be reduced substantially. Special training in the use of this type of apparatus shall be provided to the wearer (see footnote 4).
¹⁷ Protection factor for type and mode of operation as listed above.

Note 1.—Protection factors for respirators, as may be approved by the U.S. Bureau of Mines/National Institute for Occupational Safety and Health (NIOSH) according to applicable approvals for respirators for type and mode of use to protect against airborne radionuclides, may be used to the extent that they do not exceed the protection factors listed in this table. The protection factors listed in this table may not be appropriate to circumstances where chemical or other respiratory hazards exist in addition to radiological hazards. The selection and use of respirators for these circumstances should take into account applicable approvals of the U.S. Bureau of Mines/NIOSH.

Note 2.—Radioactive contaminants for which the concentration values in Table 1, column 1, Appendix B of this part are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

47 FR 19511

APPENDIX B

Concentrations in Air and Water Above Natural Background

[See notes at end of appendix]

Element (atomic number)	Isotope ¹	Table I		Table II		
		Column 1	Column 2	Column 1	Column 2	
		† Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)	† Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)	
Actinium (89)	Ac 227	5	2×10^{-12}	6×10^{-13}	8×10^{-14}	2×10^{-4}
	Ac 228	5	3×10^{-11}	9×10^{-13}	9×10^{-13}	3×10^{-4}
Americium (95)	Am 241	5	8×10^{-12}	3×10^{-12}	3×10^{-12}	9×10^{-5}
	Am 242m	5	2×10^{-9}	3×10^{-12}	6×10^{-14}	9×10^{-5}
	Am 242	5	6×10^{-12}	1×10^{-14}	2×10^{-13}	4×10^{-4}
	Am 243	5	1×10^{-10}	8×10^{-14}	4×10^{-13}	3×10^{-5}
	Am 243	5	6×10^{-12}	1×10^{-14}	2×10^{-13}	4×10^{-4}
	Am 244	5	3×10^{-10}	3×10^{-12}	9×10^{-13}	9×10^{-5}
	Am 244	5	4×10^{-12}	4×10^{-13}	1×10^{-12}	1×10^{-4}
Antimony (51)	Sb 123	5	3×10^{-9}	4×10^{-13}	2×10^{-12}	1×10^{-4}
	Sb 124	5	2×10^{-7}	8×10^{-14}	6×10^{-14}	3×10^{-5}
	Sb 125	5	1×10^{-7}	8×10^{-14}	3×10^{-14}	3×10^{-5}
	Sb 125	5	2×10^{-7}	7×10^{-14}	5×10^{-14}	2×10^{-5}
Argon (18)	A 37	Sub ²	3×10^{-7}	3×10^{-13}	2×10^{-10}	1×10^{-4}
	A 41	Sub	6×10^{-13}	1×10^{-11}	1×10^{-11}	1×10^{-4}
Arsenic (33)	As 73	5	2×10^{-9}	3×10^{-12}	7×10^{-14}	5×10^{-4}
	As 74	5	4×10^{-7}	1×10^{-11}	1×10^{-11}	5×10^{-4}
	As 76	5	3×10^{-7}	2×10^{-11}	1×10^{-11}	5×10^{-4}
	As 76	5	1×10^{-7}	2×10^{-11}	4×10^{-11}	5×10^{-5}
	As 77	5	1×10^{-7}	6×10^{-14}	4×10^{-14}	2×10^{-5}
	As 77	5	1×10^{-7}	6×10^{-14}	3×10^{-14}	2×10^{-5}
Astatine (85)	At 211	5	5×10^{-7}	2×10^{-13}	2×10^{-14}	8×10^{-5}
	At 211	5	4×10^{-7}	2×10^{-13}	1×10^{-14}	8×10^{-5}
Barium (56)	Ba 131	5	7×10^{-9}	5×10^{-13}	2×10^{-10}	2×10^{-4}
	Ba 131	5	3×10^{-9}	2×10^{-13}	1×10^{-10}	7×10^{-5}
Berkelium (97)	Bk 249	5	4×10^{-7}	3×10^{-13}	4×10^{-14}	2×10^{-4}
	Bk 249	5	1×10^{-7}	1×10^{-13}	1×10^{-14}	2×10^{-4}
Beryllium (4)	Be 7	5	9×10^{-10}	2×10^{-11}	3×10^{-11}	6×10^{-4}
	Be 7	5	1×10^{-7}	2×10^{-13}	4×10^{-14}	6×10^{-4}
Bismuth (83)	Bi 206	5	1×10^{-7}	6×10^{-13}	5×10^{-14}	2×10^{-4}
	Bi 207	5	1×10^{-7}	6×10^{-13}	4×10^{-14}	2×10^{-4}
	Bi 207	5	2×10^{-7}	2×10^{-13}	2×10^{-13}	6×10^{-5}
	Bi 210	5	1×10^{-7}	2×10^{-13}	5×10^{-14}	6×10^{-5}
	Bi 210	5	6×10^{-7}	1×10^{-13}	2×10^{-10}	4×10^{-5}
	Bi 212	5	6×10^{-7}	1×10^{-13}	2×10^{-10}	4×10^{-5}

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PART 20 • STANDARDS FOR PROTECTION AGAINST RADIATION

APPENDIX B
Concentrations in Air and Water Above Natural Background - Continued
(See notes at end of appendix)

Element (atomic number)	Isotope	Table I		Table II		
		Column 1	Column 2	Column 1	Column 2	
		Air † (μCi/ml)	Water (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	
Cobalt (27)	Co 57	S	3 × 10 ⁻⁴	3 × 10 ⁻⁷	1 × 10 ⁻⁷	5 × 10 ⁻⁴
		I	2 × 10 ⁻⁷	1 × 10 ⁻⁷	6 × 10 ⁻⁸	4 × 10 ⁻⁴
	Co 58m	S	2 × 10 ⁻⁷	8 × 10 ⁻⁷	6 × 10 ⁻⁷	3 × 10 ⁻⁷
		I	9 × 10 ⁻⁸	6 × 10 ⁻⁷	3 × 10 ⁻⁷	2 × 10 ⁻⁷
	Co 58	S	8 × 10 ⁻⁷	4 × 10 ⁻⁷	3 × 10 ⁻⁸	1 × 10 ⁻⁷
		I	5 × 10 ⁻⁹	3 × 10 ⁻⁷	2 × 10 ⁻⁸	9 × 10 ⁻⁷
Copper (29)	Co 60	S	3 × 10 ⁻⁷	1 × 10 ⁻⁷	1 × 10 ⁻⁸	3 × 10 ⁻⁷
		I	9 × 10 ⁻⁹	1 × 10 ⁻⁷	3 × 10 ⁻¹⁰	3 × 10 ⁻⁷
Copper (29)	Cu 64	S	2 × 10 ⁻⁴	1 × 10 ⁻⁷	7 × 10 ⁻⁹	3 × 10 ⁻⁷
		I	1 × 10 ⁻⁴	6 × 10 ⁻⁷	4 × 10 ⁻⁸	2 × 10 ⁻⁷
Curium (96)	Cm 242	S	1 × 10 ⁻¹⁰	7 × 10 ⁻⁹	4 × 10 ⁻¹²	2 × 10 ⁻⁷
		I	2 × 10 ⁻¹⁰	7 × 10 ⁻⁹	6 × 10 ⁻¹³	2 × 10 ⁻⁷
	Cm 243	S	6 × 10 ⁻¹²	1 × 10 ⁻⁴	2 × 10 ⁻¹²	5 × 10 ⁻⁸
		I	1 × 10 ⁻¹⁰	7 × 10 ⁻⁴	3 × 10 ⁻¹²	2 × 10 ⁻⁷
	Cm 244	S	9 × 10 ⁻¹²	3 × 10 ⁻⁴	3 × 10 ⁻¹²	7 × 10 ⁻⁸
		I	1 × 10 ⁻¹⁰	8 × 10 ⁻⁴	3 × 10 ⁻¹²	3 × 10 ⁻⁷
	Cm 245	S	5 × 10 ⁻¹²	1 × 10 ⁻⁴	2 × 10 ⁻¹²	4 × 10 ⁻⁸
		I	1 × 10 ⁻¹⁰	8 × 10 ⁻⁴	4 × 10 ⁻¹²	3 × 10 ⁻⁷
	Cm 246	S	5 × 10 ⁻¹²	1 × 10 ⁻⁴	2 × 10 ⁻¹²	4 × 10 ⁻⁸
		I	1 × 10 ⁻¹⁰	8 × 10 ⁻⁴	4 × 10 ⁻¹²	3 × 10 ⁻⁷
	Cm 247	S	5 × 10 ⁻¹²	1 × 10 ⁻⁴	2 × 10 ⁻¹²	4 × 10 ⁻⁸
		I	1 × 10 ⁻¹⁰	6 × 10 ⁻⁴	4 × 10 ⁻¹²	2 × 10 ⁻⁷
	Cm 248	S	6 × 10 ⁻¹²	1 × 10 ⁻⁴	2 × 10 ⁻¹⁴	4 × 10 ⁻⁷
		I	1 × 10 ⁻¹¹	4 × 10 ⁻⁴	4 × 10 ⁻¹³	1 × 10 ⁻⁷
Cm 249	S	1 × 10 ⁻⁷	6 × 10 ⁻⁷	4 × 10 ⁻⁷	2 × 10 ⁻⁷	
	I	1 × 10 ⁻⁷	6 × 10 ⁻⁷	4 × 10 ⁻⁷	2 × 10 ⁻⁷	
Dysprosium (66)	Dy 163	S	3 × 10 ⁻⁴	1 × 10 ⁻⁷	9 × 10 ⁻⁸	4 × 10 ⁻⁴
		I	2 × 10 ⁻⁴	1 × 10 ⁻⁷	7 × 10 ⁻⁸	4 × 10 ⁻⁴
	Dy 166	S	2 × 10 ⁻⁷	1 × 10 ⁻⁷	8 × 10 ⁻⁹	4 × 10 ⁻⁷
Einsteinium (99)	Es 253	S	8 × 10 ⁻¹⁰	7 × 10 ⁻⁴	3 × 10 ⁻¹¹	2 × 10 ⁻⁷
		I	6 × 10 ⁻¹⁰	7 × 10 ⁻⁴	2 × 10 ⁻¹¹	2 × 10 ⁻⁷
	Es 254m	S	5 × 10 ⁻⁹	5 × 10 ⁻⁴	2 × 10 ⁻¹⁰	2 × 10 ⁻⁷
		I	6 × 10 ⁻⁹	5 × 10 ⁻⁴	2 × 10 ⁻¹⁰	2 × 10 ⁻⁷
	Es 254	S	2 × 10 ⁻¹¹	4 × 10 ⁻⁴	6 × 10 ⁻¹²	1 × 10 ⁻⁷
		I	1 × 10 ⁻¹⁰	4 × 10 ⁻⁴	4 × 10 ⁻¹²	1 × 10 ⁻⁷
	Es 255	S	5 × 10 ⁻¹⁰	8 × 10 ⁻⁴	2 × 10 ⁻¹¹	3 × 10 ⁻⁷
Bromine (68)	Br 169	S	4 × 10 ⁻¹⁰	8 × 10 ⁻⁹	1 × 10 ⁻¹¹	3 × 10 ⁻⁷
		I	6 × 10 ⁻⁷	3 × 10 ⁻⁷	3 × 10 ⁻⁸	9 × 10 ⁻⁷
	Br 171	S	4 × 10 ⁻⁷	3 × 10 ⁻⁷	1 × 10 ⁻⁸	9 × 10 ⁻⁷
Europium (63)	Eu 152	S	6 × 10 ⁻⁷	3 × 10 ⁻⁷	2 × 10 ⁻⁸	1 × 10 ⁻⁷
		I	4 × 10 ⁻⁷	3 × 10 ⁻⁷	2 × 10 ⁻⁸	6 × 10 ⁻⁷
	(T/2 = 9.2 hrs)	I	3 × 10 ⁻⁷	2 × 10 ⁻⁷	1 × 10 ⁻⁸	4 × 10 ⁻⁷
	Eu 152	S	1 × 10 ⁻⁸	2 × 10 ⁻⁷	4 × 10 ⁻¹⁰	8 × 10 ⁻⁷
	(T/2 = 13 yrs)	I	2 × 10 ⁻⁸	2 × 10 ⁻⁷	3 × 10 ⁻¹⁰	8 × 10 ⁻⁷
	Eu 154	S	4 × 10 ⁻⁹	6 × 10 ⁻⁴	1 × 10 ⁻¹⁰	2 × 10 ⁻⁷
		I	7 × 10 ⁻⁹	6 × 10 ⁻⁴	2 × 10 ⁻¹⁰	2 × 10 ⁻⁷
Eu 155	S	9 × 10 ⁻⁴	6 × 10 ⁻⁷	3 × 10 ⁻⁷	2 × 10 ⁻⁷	
	I	7 × 10 ⁻⁴	6 × 10 ⁻⁷	3 × 10 ⁻⁷	2 × 10 ⁻⁷	

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APPENDIX B

Concentrations in Air and Water Above Natural Background—Continued

(See notes at end of appendix)

Element (atomic number)	Isotope	Table I		Table II		
		Column 1	Column 2	Column 1	Column 2	
		Air † (μCi/ml)	Water (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	
Bromine (35)	Br 82	S	1×10^{-4}	6×10^{-3}	4×10^{-4}	3×10^{-4}
		I	2×10^{-7}	1×10^{-2}	6×10^{-4}	4×10^{-3}
Cadmium (48)	Cd 109	S	5×10^{-7}	5×10^{-2}	2×10^{-4}	2×10^{-4}
		I	7×10^{-4}	5×10^{-2}	3×10^{-4}	3×10^{-4}
	Cd 115m	S	4×10^{-4}	7×10^{-2}	1×10^{-4}	3×10^{-4}
		I	4×10^{-4}	7×10^{-2}	1×10^{-4}	3×10^{-4}
Cd 113	S	2×10^{-7}	1×10^{-2}	6×10^{-4}	3×10^{-3}	
	I	3×10^{-7}	1×10^{-2}	6×10^{-4}	4×10^{-3}	
Calcium (20)	Ca 45	S	3×10^{-6}	3×10^{-2}	1×10^{-4}	9×10^{-4}
		I	1×10^{-7}	5×10^{-2}	4×10^{-4}	2×10^{-4}
	Ca 47	S	2×10^{-7}	1×10^{-2}	6×10^{-4}	5×10^{-3}
Californium (98)	Cf 249	S	2×10^{-12}	1×10^{-4}	5×10^{-14}	4×10^{-4}
		I	1×10^{-10}	7×10^{-4}	5×10^{-12}	2×10^{-3}
	Cf 250	S	5×10^{-12}	4×10^{-4}	2×10^{-13}	1×10^{-3}
		I	1×10^{-10}	7×10^{-4}	3×10^{-12}	3×10^{-3}
	Cf 251	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	4×10^{-3}
		I	1×10^{-10}	8×10^{-4}	3×10^{-12}	3×10^{-3}
	Cf 252	S	6×10^{-11}	2×10^{-4}	2×10^{-12}	7×10^{-4}
		I	3×10^{-11}	2×10^{-4}	1×10^{-12}	7×10^{-4}
	Cf 253	S	8×10^{-10}	4×10^{-4}	3×10^{-11}	1×10^{-4}
		I	8×10^{-10}	4×10^{-4}	3×10^{-11}	1×10^{-4}
	Cf 254	S	5×10^{-12}	4×10^{-4}	2×10^{-13}	1×10^{-7}
I		5×10^{-12}	4×10^{-4}	2×10^{-13}	1×10^{-7}	
Carbon (6)	C 14 (CO ₂)	S	4×10^{-4}	2×10^{-7}	1×10^{-7}	6×10^{-3}
		Sub	5×10^{-5}		1×10^{-4}	
Cerium (58)	Ce 141	S	4×10^{-7}	3×10^{-3}	2×10^{-9}	9×10^{-3}
		I	2×10^{-7}	3×10^{-3}	5×10^{-9}	9×10^{-3}
	Ce 143	S	3×10^{-7}	1×10^{-3}	9×10^{-9}	4×10^{-3}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-3}
	Ce 144	S	1×10^{-9}	3×10^{-4}	3×10^{-14}	1×10^{-3}
I		6×10^{-9}	3×10^{-4}	2×10^{-10}	1×10^{-3}	
Cesium (55)	Cs 131	S	1×10^{-7}	7×10^{-2}	4×10^{-7}	2×10^{-3}
		I	3×10^{-8}	3×10^{-2}	1×10^{-7}	9×10^{-4}
	Cs 134m	S	4×10^{-4}	2×10^{-2}	1×10^{-4}	6×10^{-3}
		I	6×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
	Cs 134	S	4×10^{-8}	3×10^{-4}	1×10^{-9}	9×10^{-3}
		I	1×10^{-8}	1×10^{-3}	4×10^{-10}	4×10^{-3}
	Cs 135	S	5×10^{-7}	3×10^{-2}	2×10^{-8}	1×10^{-4}
		I	9×10^{-8}	7×10^{-2}	3×10^{-9}	2×10^{-4}
	Cs 136	S	4×10^{-7}	2×10^{-2}	1×10^{-8}	9×10^{-4}
		I	2×10^{-7}	2×10^{-2}	6×10^{-9}	6×10^{-4}
Cs 137	S	6×10^{-6}	4×10^{-4}	2×10^{-8}	2×10^{-3}	
	I	1×10^{-4}	1×10^{-3}	5×10^{-10}	4×10^{-3}	
Chlorine (17)	Cl 36	S	4×10^{-7}	2×10^{-2}	1×10^{-8}	8×10^{-3}
		I	2×10^{-4}	2×10^{-2}	8×10^{-10}	6×10^{-3}
	Cl 38	S	2×10^{-4}	1×10^{-2}	9×10^{-8}	4×10^{-4}
Chromium (24)	Cr 51	S	1×10^{-7}	5×10^{-2}	4×10^{-7}	2×10^{-3}
		I	2×10^{-4}	5×10^{-2}	8×10^{-8}	2×10^{-3}

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APPENDIX B
 Concentrations in Air and Water Above Natural Background—Continued
 (See notes at end of appendix)

Element (atomic number)	Isotope [†]	Table I		Table II		
		Column 1	Column 2	Column 1	Column 2	
		Air † (μCi/ml)	Water (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	
Fermium (100)	Fm 254	5	4 × 10 ⁻⁴	4 × 10 ⁻³	2 × 10 ⁻⁴	1 × 10 ⁻⁴
		1	7 × 10 ⁻⁴	4 × 10 ⁻³	3 × 10 ⁻⁴	1 × 10 ⁻⁴
	Fm 255	5	2 × 10 ⁻⁴	1 × 10 ⁻³	6 × 10 ⁻⁴	1 × 10 ⁻⁴
		1	1 × 10 ⁻⁴	3 × 10 ⁻³	4 × 10 ⁻⁴	2 × 10 ⁻⁴
	Fm 256	5	3 × 10 ⁻⁴	2 × 10 ⁻³	1 × 10 ⁻⁴	9 × 10 ⁻⁵
		1	2 × 10 ⁻⁴	3 × 10 ⁻³	6 × 10 ⁻⁴	9 × 10 ⁻⁵
Fluorine (9)	F 18	5	5 × 10 ⁻⁴	2 × 10 ⁻³	2 × 10 ⁻⁴	8 × 10 ⁻⁵
		1	3 × 10 ⁻⁴	1 × 10 ⁻³	9 × 10 ⁻⁴	5 × 10 ⁻⁵
Gadolinium (64)	Gd 153	5	2 × 10 ⁻⁷	6 × 10 ⁻⁷	8 × 10 ⁻⁷	3 × 10 ⁻⁷
		1	9 × 10 ⁻⁷	6 × 10 ⁻⁷	3 × 10 ⁻⁷	3 × 10 ⁻⁷
	Gd 159	5	5 × 10 ⁻⁷	2 × 10 ⁻⁷	2 × 10 ⁻⁷	8 × 10 ⁻⁸
Gallium (31)	Ga 72	5	2 × 10 ⁻⁷	1 × 10 ⁻⁷	8 × 10 ⁻⁸	4 × 10 ⁻⁸
		1	2 × 10 ⁻⁷	1 × 10 ⁻⁷	6 × 10 ⁻⁸	4 × 10 ⁻⁸
Germanium (32)	Ge 71	5	1 × 10 ⁻⁷	5 × 10 ⁻⁸	4 × 10 ⁻⁸	2 × 10 ⁻⁸
		1	6 × 10 ⁻⁸	5 × 10 ⁻⁸	3 × 10 ⁻⁸	2 × 10 ⁻⁸
Gold (79)	Au 196	5	1 × 10 ⁻⁴	5 × 10 ⁻⁴	4 × 10 ⁻⁴	2 × 10 ⁻⁴
		1	6 × 10 ⁻⁴	4 × 10 ⁻⁴	3 × 10 ⁻⁴	1 × 10 ⁻⁴
	Au 198	5	3 × 10 ⁻⁷	2 × 10 ⁻⁷	1 × 10 ⁻⁷	3 × 10 ⁻⁸
		1	3 × 10 ⁻⁷	1 × 10 ⁻⁷	8 × 10 ⁻⁸	8 × 10 ⁻⁸
Au 199	5	1 × 10 ⁻⁴	5 × 10 ⁻⁴	4 × 10 ⁻⁴	3 × 10 ⁻⁴	
	1	8 × 10 ⁻⁴	4 × 10 ⁻⁴	3 × 10 ⁻⁴	3 × 10 ⁻⁴	
Hafnium (72)	Hf 181	5	4 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻³	7 × 10 ⁻⁴
		1	7 × 10 ⁻³	2 × 10 ⁻³	3 × 10 ⁻³	7 × 10 ⁻⁴
Hassium (67)	Hs 166	5	2 × 10 ⁻⁷	9 × 10 ⁻⁸	7 × 10 ⁻⁸	3 × 10 ⁻⁸
		1	2 × 10 ⁻⁷	9 × 10 ⁻⁸	6 × 10 ⁻⁸	3 × 10 ⁻⁸
Hydrogen (1)	H2	5	5 × 10 ⁻⁴	1 × 10 ⁻³	2 × 10 ⁻⁴	3 × 10 ⁻⁴
		1	5 × 10 ⁻⁴	1 × 10 ⁻³	2 × 10 ⁻⁴	3 × 10 ⁻⁴
Indium (49)	In 113m	5	2 × 10 ⁻³	4 × 10 ⁻³	4 × 10 ⁻³	1 × 10 ⁻³
		1	6 × 10 ⁻³	4 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻³
	In 114m	5	1 × 10 ⁻³	5 × 10 ⁻³	4 × 10 ⁻³	2 × 10 ⁻³
		1	2 × 10 ⁻³	5 × 10 ⁻³	7 × 10 ⁻³	2 × 10 ⁻³
	In 115m	5	2 × 10 ⁻³	1 × 10 ⁻³	1 × 10 ⁻³	4 × 10 ⁻⁴
		1	3 × 10 ⁻³	1 × 10 ⁻³	6 × 10 ⁻³	4 × 10 ⁻⁴
In 115	5	3 × 10 ⁻³	2 × 10 ⁻³	9 × 10 ⁻³	9 × 10 ⁻⁴	
	1	3 × 10 ⁻³	5 × 10 ⁻³	1 × 10 ⁻³	9 × 10 ⁻⁴	
Iodine (53)	I 125	5	5 × 10 ⁻⁴	4 × 10 ⁻⁴	8 × 10 ⁻⁴	2 × 10 ⁻⁴
		1	2 × 10 ⁻⁴	6 × 10 ⁻⁴	6 × 10 ⁻⁴	2 × 10 ⁻⁴
	I 126	5	8 × 10 ⁻⁴	5 × 10 ⁻⁴	9 × 10 ⁻⁴	3 × 10 ⁻⁴
		1	2 × 10 ⁻⁴	3 × 10 ⁻⁴	1 × 10 ⁻⁴	9 × 10 ⁻⁵
	I 129	5	2 × 10 ⁻⁴	1 × 10 ⁻⁴	2 × 10 ⁻⁴	6 × 10 ⁻⁵
		1	7 × 10 ⁻⁴	6 × 10 ⁻⁴	2 × 10 ⁻⁴	2 × 10 ⁻⁴
	I 131	5	9 × 10 ⁻⁴	6 × 10 ⁻⁴	6 × 10 ⁻⁴	1 × 10 ⁻⁴
		1	3 × 10 ⁻⁴	2 × 10 ⁻⁴	1 × 10 ⁻⁴	6 × 10 ⁻⁵
	I 132	5	2 × 10 ⁻⁴	2 × 10 ⁻⁴	3 × 10 ⁻⁴	8 × 10 ⁻⁵
		1	9 × 10 ⁻⁴	5 × 10 ⁻⁴	3 × 10 ⁻⁴	2 × 10 ⁻⁴
	I 133	5	2 × 10 ⁻⁴	2 × 10 ⁻⁴	4 × 10 ⁻⁴	1 × 10 ⁻⁴
1		2 × 10 ⁻⁴	1 × 10 ⁻⁴	7 × 10 ⁻⁴	4 × 10 ⁻⁴	
I 134	5	5 × 10 ⁻⁴	4 × 10 ⁻⁴	6 × 10 ⁻⁴	2 × 10 ⁻⁴	

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APPENDIX B
Concentrations in Air and Water Above Natural Background—Continued
 (See notes at end of appendix)

Element (atomic number)	Isotope ¹	Table I		Table II		
		Column 1	Column 2	Column 1	Column 2	
		† (μCi/ml) Air	(μCi/ml) Water	(μCi/ml) Air	(μCi/ml) Water	
Iodine (53)	I 134	I	3 × 10 ⁻⁴	2 × 10 ⁻³	1 × 10 ⁻⁷	6 × 10 ⁻⁴
	I 135	S	1 × 10 ⁻⁷	7 × 10 ⁻⁴	1 × 10 ⁻⁷	4 × 10 ⁻⁴
Bridium (77)	B 190	S	4 × 10 ⁻⁷	3 × 10 ⁻³	1 × 10 ⁻⁴	7 × 10 ⁻⁴
		I	1 × 10 ⁻⁴	6 × 10 ⁻³	4 × 10 ⁻⁴	2 × 10 ⁻⁴
	B 192	S	4 × 10 ⁻⁷	2 × 10 ⁻³	1 × 10 ⁻⁴	2 × 10 ⁻⁴
	B 194	S	1 × 10 ⁻⁷	1 × 10 ⁻³	4 × 10 ⁻⁴	4 × 10 ⁻⁴
Iron (26)	Fe 55	S	3 × 10 ⁻⁷	1 × 10 ⁻³	9 × 10 ⁻⁴	3 × 10 ⁻⁴
	Fe 59	S	2 × 10 ⁻⁷	9 × 10 ⁻⁴	5 × 10 ⁻⁴	3 × 10 ⁻⁴
Krypton (36)	Kr 85m	Sub	9 × 10 ⁻⁷	2 × 10 ⁻³	3 × 10 ⁻⁴	8 × 10 ⁻⁴
	Kr 85	I	1 × 10 ⁻⁴	7 × 10 ⁻³	3 × 10 ⁻⁴	2 × 10 ⁻⁴
	Kr 87	Sub	1 × 10 ⁻⁴	2 × 10 ⁻³	3 × 10 ⁻⁴	6 × 10 ⁻⁴
	Kr 86	Sub	3 × 10 ⁻⁴	2 × 10 ⁻³	3 × 10 ⁻⁴	8 × 10 ⁻⁴
Lanthanum (57)	La 140	S	6 × 10 ⁻⁴	1 × 10 ⁻³	1 × 10 ⁻⁷	
		I	1 × 10 ⁻⁷	7 × 10 ⁻⁴	3 × 10 ⁻⁷	
Lead (82)	Pb 203	S	1 × 10 ⁻⁷	7 × 10 ⁻⁴	4 × 10 ⁻⁴	2 × 10 ⁻⁴
		I	2 × 10 ⁻⁴	1 × 10 ⁻³	9 × 10 ⁻⁴	4 × 10 ⁻⁴
	Pb 210	S	1 × 10 ⁻¹⁰	4 × 10 ⁻⁴	4 × 10 ⁻¹¹	1 × 10 ⁻⁷
		I	2 × 10 ⁻¹⁰	5 × 10 ⁻³	6 × 10 ⁻¹¹	2 × 10 ⁻⁴
Lutetium (71)	Lu 177	S	2 × 10 ⁻⁴	6 × 10 ⁻⁴	6 × 10 ⁻¹⁰	2 × 10 ⁻⁴
		I	3 × 10 ⁻⁴	3 × 10 ⁻⁴	7 × 10 ⁻¹⁰	5 × 10 ⁻⁴
Manganese (25)	Mn 53	S	6 × 10 ⁻⁷	3 × 10 ⁻³	2 × 10 ⁻⁴	1 × 10 ⁻⁴
		I	5 × 10 ⁻⁷	3 × 10 ⁻³	2 × 10 ⁻⁴	1 × 10 ⁻⁴
	Mn 54	S	2 × 10 ⁻⁷	1 × 10 ⁻³	7 × 10 ⁻⁴	3 × 10 ⁻⁴
		I	1 × 10 ⁻⁷	9 × 10 ⁻⁴	5 × 10 ⁻⁴	3 × 10 ⁻⁴
Mercury (80)	Hg 197m	S	4 × 10 ⁻⁷	4 × 10 ⁻³	1 × 10 ⁻⁴	1 × 10 ⁻⁴
		I	4 × 10 ⁻⁴	3 × 10 ⁻³	1 × 10 ⁻⁴	1 × 10 ⁻⁴
	Hg 197	S	8 × 10 ⁻⁷	4 × 10 ⁻³	2 × 10 ⁻⁴	1 × 10 ⁻⁴
		I	3 × 10 ⁻⁷	3 × 10 ⁻³	2 × 10 ⁻⁴	1 × 10 ⁻⁴
Molybdenum (42)	Hg 203	S	7 × 10 ⁻⁷	6 × 10 ⁻³	3 × 10 ⁻⁴	2 × 10 ⁻⁴
		I	8 × 10 ⁻⁷	5 × 10 ⁻³	2 × 10 ⁻⁴	2 × 10 ⁻⁴
		I	1 × 10 ⁻⁷	1 × 10 ⁻³	9 × 10 ⁻⁴	5 × 10 ⁻⁴
Neodymium (60)	Nd 99	S	7 × 10 ⁻⁷	5 × 10 ⁻³	3 × 10 ⁻⁴	2 × 10 ⁻⁴
		I	2 × 10 ⁻⁷	1 × 10 ⁻³	7 × 10 ⁻⁴	4 × 10 ⁻⁴
Neodymium (60)	Nd 144	S	8 × 10 ⁻¹¹	2 × 10 ⁻³	3 × 10 ⁻¹¹	7 × 10 ⁻⁴
		I	3 × 10 ⁻¹⁰	3 × 10 ⁻³	1 × 10 ⁻¹¹	8 × 10 ⁻⁴
	Nd 147	S	4 × 10 ⁻⁷	2 × 10 ⁻³	1 × 10 ⁻⁴	6 × 10 ⁻⁴
		I	2 × 10 ⁻⁷	2 × 10 ⁻³	8 × 10 ⁻⁴	6 × 10 ⁻⁴
	Nd 149	S	2 × 10 ⁻⁴	8 × 10 ⁻³	6 × 10 ⁻⁴	3 × 10 ⁻⁴
		I	1 × 10 ⁻⁴	6 × 10 ⁻³	5 × 10 ⁻⁴	3 × 10 ⁻⁴

APPENDIX B
 Concentrations in Air and Water Above Natural Background—Continued
 (See notes at end of appendix)

Element (atomic number)	Isotope ¹	Table I		Table II		
		Column 1	Column 2	Column 1	Column 2	
		† (μCi/ml)	(μCi/ml)	(μCi/ml)	(μCi/ml)	
Neptunium (93)	Np 237	5	4 × 10 ⁻¹²	9 × 10 ⁻⁷	1 × 10 ⁻¹¹	3 × 10 ⁻⁴
		1	1 × 10 ⁻¹⁰	9 × 10 ⁻⁴	4 × 10 ⁻¹¹	3 × 10 ⁻²
	Np 239	5	6 × 10 ⁻⁷	4 × 10 ⁻²	3 × 10 ⁻⁴	1 × 10 ⁻⁴
		1	7 × 10 ⁻⁷	4 × 10 ⁻²	3 × 10 ⁻⁴	1 × 10 ⁻⁴
Nickel (28)	Ni 59	5	3 × 10 ⁻⁷	6 × 10 ⁻²	3 × 10 ⁻⁴	3 × 10 ⁻⁴
		1	3 × 10 ⁻⁷	6 × 10 ⁻²	3 × 10 ⁻⁴	3 × 10 ⁻³
	Ni 63	5	6 × 10 ⁻⁴	6 × 10 ⁻⁴	2 × 10 ⁻⁴	3 × 10 ⁻³
		1	3 × 10 ⁻⁷	3 × 10 ⁻²	1 × 10 ⁻⁴	7 × 10 ⁻⁴
	Ni 65	5	9 × 10 ⁻⁷	4 × 10 ⁻²	3 × 10 ⁻⁴	1 × 10 ⁻⁴
		1	5 × 10 ⁻⁷	3 × 10 ⁻²	2 × 10 ⁻⁴	1 × 10 ⁻⁴
	Niobium (Columbium) (41)	Nb 93m	5	1 × 10 ⁻⁷	1 × 10 ⁻²	4 × 10 ⁻⁴
	1	3 × 10 ⁻⁷	1 × 10 ⁻²	5 × 10 ⁻⁴	4 × 10 ⁻⁴	
	Nb 95	5	5 × 10 ⁻⁷	3 × 10 ⁻²	3 × 10 ⁻⁴	1 × 10 ⁻⁴
		1	1 × 10 ⁻⁷	3 × 10 ⁻²	3 × 10 ⁻⁴	1 × 10 ⁻⁴
	Nb 97	5	6 × 10 ⁻⁴	3 × 10 ⁻²	3 × 10 ⁻⁷	9 × 10 ⁻⁴
		1	5 × 10 ⁻⁴	3 × 10 ⁻²	3 × 10 ⁻⁷	3 × 10 ⁻⁴
Osmium (76)	Os 185	5	5 × 10 ⁻⁷	2 × 10 ⁻²	2 × 10 ⁻⁴	7 × 10 ⁻⁴
		1	5 × 10 ⁻⁷	2 × 10 ⁻²	2 × 10 ⁻⁴	7 × 10 ⁻⁴
	Os 191m	5	3 × 10 ⁻⁴	7 × 10 ⁻²	6 × 10 ⁻⁷	3 × 10 ⁻³
		1	9 × 10 ⁻⁴	7 × 10 ⁻²	3 × 10 ⁻⁷	2 × 10 ⁻³
	Os 191	5	1 × 10 ⁻⁴	5 × 10 ⁻³	4 × 10 ⁻⁴	2 × 10 ⁻⁴
	1	4 × 10 ⁻⁷	5 × 10 ⁻³	1 × 10 ⁻⁴	3 × 10 ⁻⁴	
	Os 193	5	4 × 10 ⁻⁷	2 × 10 ⁻²	1 × 10 ⁻⁴	6 × 10 ⁻⁴
		1	3 × 10 ⁻⁷	2 × 10 ⁻²	9 × 10 ⁻⁴	5 × 10 ⁻⁴
Palladium (46)	Pd 103	5	1 × 10 ⁻⁴	1 × 10 ⁻²	5 × 10 ⁻⁴	3 × 10 ⁻⁴
		1	7 × 10 ⁻⁷	8 × 10 ⁻³	3 × 10 ⁻⁴	3 × 10 ⁻⁴
	Pd 109	5	6 × 10 ⁻⁷	3 × 10 ⁻²	2 × 10 ⁻⁴	9 × 10 ⁻⁴
		1	1 × 10 ⁻⁷	2 × 10 ⁻²	1 × 10 ⁻⁴	7 × 10 ⁻⁴
Phosphorus (15)	P 32	5	7 × 10 ⁻⁴	5 × 10 ⁻⁴	3 × 10 ⁻⁴	2 × 10 ⁻⁴
		1	8 × 10 ⁻⁴	7 × 10 ⁻⁴	3 × 10 ⁻⁴	2 × 10 ⁻⁴
Platinum (78)	Pt 191	5	8 × 10 ⁻⁷	4 × 10 ⁻²	3 × 10 ⁻⁴	1 × 10 ⁻⁴
		1	6 × 10 ⁻⁷	3 × 10 ⁻²	5 × 10 ⁻⁴	1 × 10 ⁻⁴
	Pt 193m	5	7 × 10 ⁻⁴	3 × 10 ⁻²	3 × 10 ⁻⁷	1 × 10 ⁻³
		1	5 × 10 ⁻⁴	3 × 10 ⁻²	3 × 10 ⁻⁷	1 × 10 ⁻³
	* Pt 193	5	1 × 10 ⁻¹¹	3 × 10 ⁻²	4 × 10 ⁻⁴	9 × 10 ⁻⁴
	1	3 × 10 ⁻⁷	5 × 10 ⁻²	1 × 10 ⁻⁴	2 × 10 ⁻⁴	
	Pt 197m	5	6 × 10 ⁻⁴	3 × 10 ⁻²	2 × 10 ⁻⁷	1 × 10 ⁻³
		1	5 × 10 ⁻⁴	3 × 10 ⁻²	2 × 10 ⁻⁷	9 × 10 ⁻⁴
	Pt 197	5	8 × 10 ⁻⁷	4 × 10 ⁻²	3 × 10 ⁻⁴	1 × 10 ⁻⁴
		1	6 × 10 ⁻⁷	3 × 10 ⁻²	2 × 10 ⁻⁴	1 × 10 ⁻⁴
Plutonium (94)	Pu 238	5	2 × 10 ⁻¹²	1 × 10 ⁻⁴	7 × 10 ⁻¹¹	5 × 10 ⁻⁴
		1	3 × 10 ⁻¹¹	8 × 10 ⁻⁴	1 × 10 ⁻¹²	3 × 10 ⁻⁴
	Pu 239	5	2 × 10 ⁻¹²	1 × 10 ⁻⁴	6 × 10 ⁻¹¹	5 × 10 ⁻⁴
		1	4 × 10 ⁻¹¹	8 × 10 ⁻⁴	1 × 10 ⁻¹²	3 × 10 ⁻⁴
	Pu 240	5	2 × 10 ⁻¹²	1 × 10 ⁻⁴	4 × 10 ⁻¹¹	5 × 10 ⁻⁴
	1	4 × 10 ⁻¹¹	8 × 10 ⁻⁴	1 × 10 ⁻¹²	3 × 10 ⁻⁴	
	Pu 241	5	9 × 10 ⁻¹¹	7 × 10 ⁻⁴	3 × 10 ⁻¹²	2 × 10 ⁻⁴
		1	4 × 10 ⁻⁸	4 × 10 ⁻²	1 × 10 ⁻⁸	1 × 10 ⁻⁴

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PART 20 • STANDARDS FOR PROTECTION AGAINST RADIATION

APPENDIX B
Concentrations in Air and Water Above Natural Background—Continued
 (See notes at end of appendix)

Element (atomic number)	Isotope	Table I		Table II	
		Column 1	Column 2	Column 1	Column 2
		Air † (μCi/ml)	Water (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)
Plutonium (94)	242	3 × 10 ⁻¹²	1 × 10 ⁻¹⁴	2 × 10 ⁻¹²	3 × 10 ⁻¹⁴
	243	4 × 10 ⁻¹¹	9 × 10 ⁻¹⁴	1 × 10 ⁻¹¹	3 × 10 ⁻¹⁴
	244	3 × 10 ⁻¹⁴	1 × 10 ⁻¹⁴	6 × 10 ⁻¹⁴	3 × 10 ⁻¹⁴
	244	3 × 10 ⁻¹²	1 × 10 ⁻¹⁴	6 × 10 ⁻¹¹	4 × 10 ⁻¹⁴
Polonium (84)	210	3 × 10 ⁻¹¹	3 × 10 ⁻¹⁴	1 × 10 ⁻¹¹	1 × 10 ⁻¹⁴
	210	3 × 10 ⁻¹⁴	2 × 10 ⁻¹⁴	3 × 10 ⁻¹¹	7 × 10 ⁻¹⁴
Protactinium (91)	231	3 × 10 ⁻¹⁴	6 × 10 ⁻¹⁴	7 × 10 ⁻¹⁴	3 × 10 ⁻¹⁴
	231	1 × 10 ⁻¹²	9 × 10 ⁻¹⁴	4 × 10 ⁻¹²	3 × 10 ⁻¹⁴
Promethium (61)	147	6 × 10 ⁻¹⁴	6 × 10 ⁻¹⁴	3 × 10 ⁻¹⁴	3 × 10 ⁻¹⁴
	149	1 × 10 ⁻¹²	6 × 10 ⁻¹⁴	3 × 10 ⁻¹²	3 × 10 ⁻¹⁴
Protactinium (91)	230	3 × 10 ⁻¹⁴	7 × 10 ⁻¹⁴	6 × 10 ⁻¹¹	2 × 10 ⁻¹⁴
	231	6 × 10 ⁻¹⁴	7 × 10 ⁻¹⁴	3 × 10 ⁻¹¹	3 × 10 ⁻¹⁴
Radium (88)	223	1 × 10 ⁻¹¹	3 × 10 ⁻¹⁴	4 × 10 ⁻¹¹	9 × 10 ⁻¹⁴
	223	6 × 10 ⁻¹²	4 × 10 ⁻¹⁴	3 × 10 ⁻¹²	3 × 10 ⁻¹⁴
	224	3 × 10 ⁻¹²	3 × 10 ⁻¹⁴	6 × 10 ⁻¹²	1 × 10 ⁻¹⁴
	226	2 × 10 ⁻¹⁴	2 × 10 ⁻¹⁴	6 × 10 ⁻¹¹	7 × 10 ⁻¹⁴
	226	2 × 10 ⁻¹⁴	1 × 10 ⁻¹⁴	8 × 10 ⁻¹¹	4 × 10 ⁻¹⁴
	226	7 × 10 ⁻¹¹	7 × 10 ⁻¹⁴	3 × 10 ⁻¹¹	3 × 10 ⁻¹⁴
Radium (88)	226	3 × 10 ⁻¹¹	4 × 10 ⁻¹⁴	3 × 10 ⁻¹¹	3 × 10 ⁻¹⁴
	226	7 × 10 ⁻¹¹	6 × 10 ⁻¹⁴	2 × 10 ⁻¹¹	3 × 10 ⁻¹⁴
Radium (86)	220	4 × 10 ⁻¹¹	7 × 10 ⁻¹⁴	2 × 10 ⁻¹¹	3 × 10 ⁻¹⁴
	220	3 × 10 ⁻¹²	1 × 10 ⁻¹⁴	1 × 10 ⁻¹²	1 × 10 ⁻¹⁴
Radium (88)	223	3 × 10 ⁻¹⁴	2 × 10 ⁻¹⁴	3 × 10 ⁻¹⁴	6 × 10 ⁻¹⁴
	223	3 × 10 ⁻¹⁴	2 × 10 ⁻¹⁴	9 × 10 ⁻¹⁴	3 × 10 ⁻¹⁴
	226	6 × 10 ⁻¹²	3 × 10 ⁻¹⁴	3 × 10 ⁻¹²	9 × 10 ⁻¹⁴
	226	3 × 10 ⁻¹²	1 × 10 ⁻¹⁴	6 × 10 ⁻¹²	5 × 10 ⁻¹⁴
	226	9 × 10 ⁻¹⁴	7 × 10 ⁻¹⁴	3 × 10 ⁻¹²	3 × 10 ⁻¹⁴
	226	5 × 10 ⁻¹²	4 × 10 ⁻¹⁴	2 × 10 ⁻¹²	3 × 10 ⁻¹⁴
Radium (88)	226	4 × 10 ⁻¹²	3 × 10 ⁻¹⁴	1 × 10 ⁻¹²	6 × 10 ⁻¹⁴
	226	2 × 10 ⁻¹²	9 × 10 ⁻¹⁴	6 × 10 ⁻¹²	3 × 10 ⁻¹⁴
Radium (88)	226	8 × 10 ⁻¹²	4 × 10 ⁻¹⁴	3 × 10 ⁻¹²	1 × 10 ⁻¹⁴
	226	6 × 10 ⁻¹²	3 × 10 ⁻¹⁴	3 × 10 ⁻¹²	1 × 10 ⁻¹⁴
Radium (88)	226	8 × 10 ⁻¹²	4 × 10 ⁻¹⁴	3 × 10 ⁻¹²	1 × 10 ⁻¹⁴
	226	3 × 10 ⁻¹²	3 × 10 ⁻¹⁴	2 × 10 ⁻¹²	1 × 10 ⁻¹⁴
Radium (88)	226	7 × 10 ⁻¹²	7 × 10 ⁻¹⁴	2 × 10 ⁻¹²	2 × 10 ⁻¹⁴
	226	3 × 10 ⁻¹²	3 × 10 ⁻¹⁴	2 × 10 ⁻¹²	1 × 10 ⁻¹⁴
Radium (88)	226	7 × 10 ⁻¹²	3 × 10 ⁻¹⁴	2 × 10 ⁻¹²	2 × 10 ⁻¹⁴
	226	7 × 10 ⁻¹²	3 × 10 ⁻¹⁴	2 × 10 ⁻¹²	2 × 10 ⁻¹⁴

APPENDIX B
 Concentrations in Air and Water Above Natural Background—Continued
 (See notes at end of appendix)

Element (atomic number)	Isotope	Table I		Table II		
		Column 1	Column 2	Column 1	Column 2	
		Air † (μCi/ml)	Water (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	
Ruthenium (44)	Ru 97	5	2 × 10 ⁻⁴	1 × 10 ⁻³	6 × 10 ⁻⁴	4 × 10 ⁻⁴
		I	2 × 10 ⁻⁴	1 × 10 ⁻³	6 × 10 ⁻⁴	3 × 10 ⁻⁴
	Ru 103	5	5 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	6 × 10 ⁻⁴
		I	6 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	6 × 10 ⁻⁴
	Ru 106	5	7 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
Samarium (62)	Sm 147	5	5 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	6 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
	Sm 151	5	4 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	1 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
	Sm 153	5	3 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
Scandium (21)	Sc 46	5	4 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	2 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
	Sc 47	5	6 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	5 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
	Sc 48	5	2 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
Selenium (34)	Se 75	5	1 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	1 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
Silicon (14)	Si 31	5	6 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
Silver (47)	Ag 105	5	1 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	8 × 10 ⁻⁹	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
	Ag 110m	5	2 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	1 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
	Ag 111	5	2 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
Sodium (11)	Na 22	5	2 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	9 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
Strontium (38)	Sr 85m	5	1 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	4 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
	Sr 87	5	2 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	1 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
	Sr 89	5	3 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	4 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
	Sr 90	5	1 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	3 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
	Sr 91	5	4 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	3 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
Sr 92	5	4 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴	
Sulfur (16)	S 33	5	3 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	3 × 10 ⁻⁷	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
Tellurium (73)	Te 132	5	4 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴
		I	2 × 10 ⁻⁸	2 × 10 ⁻³	2 × 10 ⁻³	1 × 10 ⁻⁴

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APPENDIX B
 Concentrations in Air and Water Above Natural Background—Continued
 (See notes at end of appendix)

Element (atomic number)	Isotope	Table I		Table II		
		Column 1	Column 2	Column 1	Column 2	
		† Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)	† Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)	
Technetium (43)	Tc 96m	5	8×10^{-7}	4×10^{-7}	3×10^{-6}	1×10^{-6}
		1	3×10^{-7}	3×10^{-7}	1×10^{-6}	1×10^{-6}
	Tc 96	5	6×10^{-7}	3×10^{-7}	2×10^{-6}	1×10^{-6}
		1	2×10^{-7}	1×10^{-7}	6×10^{-6}	5×10^{-6}
	Tc 97m	5	2×10^{-6}	1×10^{-6}	8×10^{-6}	4×10^{-6}
		1	2×10^{-7}	5×10^{-8}	3×10^{-6}	2×10^{-6}
	Tc 97	5	1×10^{-6}	5×10^{-7}	4×10^{-6}	2×10^{-6}
		1	3×10^{-7}	2×10^{-7}	1×10^{-6}	6×10^{-6}
	Tc 99m	5	4×10^{-7}	2×10^{-7}	1×10^{-6}	6×10^{-6}
	1	1×10^{-7}	6×10^{-8}	5×10^{-7}	3×10^{-6}	
Tc 99	5	2×10^{-6}	1×10^{-6}	7×10^{-6}	3×10^{-6}	
	1	6×10^{-7}	3×10^{-7}	2×10^{-6}	2×10^{-6}	
Tellurium (52)	Te 125m	5	4×10^{-7}	3×10^{-7}	1×10^{-6}	2×10^{-6}
		1	1×10^{-7}	3×10^{-8}	4×10^{-6}	1×10^{-6}
	Te 127m	5	1×10^{-7}	2×10^{-8}	5×10^{-6}	6×10^{-6}
		1	4×10^{-8}	2×10^{-8}	1×10^{-6}	5×10^{-6}
	Te 127	5	2×10^{-6}	8×10^{-7}	6×10^{-6}	3×10^{-6}
		1	9×10^{-7}	5×10^{-7}	3×10^{-6}	2×10^{-6}
	Te 129m	5	8×10^{-8}	1×10^{-8}	3×10^{-6}	3×10^{-6}
		1	3×10^{-8}	6×10^{-9}	1×10^{-6}	2×10^{-6}
	Te 129	5	5×10^{-8}	2×10^{-8}	2×10^{-6}	8×10^{-6}
		1	4×10^{-8}	3×10^{-8}	1×10^{-6}	8×10^{-6}
Te 131m	5	4×10^{-7}	2×10^{-7}	1×10^{-6}	6×10^{-6}	
	1	2×10^{-7}	1×10^{-7}	6×10^{-6}	4×10^{-6}	
Te 132	5	2×10^{-7}	9×10^{-8}	7×10^{-6}	3×10^{-6}	
	1	1×10^{-7}	6×10^{-8}	4×10^{-6}	2×10^{-6}	
Terbium (65)	Tb 160	5	1×10^{-7}	1×10^{-7}	3×10^{-6}	4×10^{-6}
		1	3×10^{-8}	1×10^{-8}	1×10^{-6}	4×10^{-6}
Thallium (81)	Tl 200	5	3×10^{-6}	1×10^{-6}	9×10^{-6}	4×10^{-6}
		1	1×10^{-6}	7×10^{-7}	4×10^{-6}	2×10^{-6}
	Tl 201	5	2×10^{-6}	9×10^{-7}	7×10^{-6}	3×10^{-6}
		1	9×10^{-7}	5×10^{-7}	3×10^{-6}	2×10^{-6}
	Tl 203	5	8×10^{-7}	4×10^{-7}	3×10^{-6}	1×10^{-6}
	1	2×10^{-7}	2×10^{-7}	8×10^{-6}	7×10^{-6}	
Tl 204	5	6×10^{-7}	3×10^{-7}	2×10^{-6}	1×10^{-6}	
	1	3×10^{-7}	2×10^{-7}	9×10^{-6}	6×10^{-6}	
Thorium (90)	Th 227	5	3×10^{-10}	5×10^{-10}	1×10^{-11}	2×10^{-10}
		1	2×10^{-10}	5×10^{-10}	6×10^{-11}	2×10^{-10}
	Th 228	5	8×10^{-12}	2×10^{-12}	3×10^{-11}	7×10^{-11}
		1	6×10^{-12}	4×10^{-12}	2×10^{-11}	1×10^{-11}
	Th 230	5	2×10^{-12}	5×10^{-13}	8×10^{-12}	2×10^{-11}
		1	1×10^{-11}	8×10^{-12}	3×10^{-11}	3×10^{-11}
	Th 231	5	1×10^{-11}	7×10^{-12}	5×10^{-11}	2×10^{-11}
		1	1×10^{-11}	7×10^{-12}	4×10^{-11}	2×10^{-11}
	Th 232	5	3×10^{-11}	5×10^{-12}	1×10^{-11}	2×10^{-11}
		1	3×10^{-11}	1×10^{-11}	1×10^{-11}	4×10^{-11}
Th natural	5	6×10^{-11}	6×10^{-11}	2×10^{-11}	2×10^{-11}	
	1	6×10^{-11}	6×10^{-11}	2×10^{-11}	2×10^{-11}	

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APPENDIX B
 Concentrations in Air and Water Above Natural Background—Continued
 (See notes at end of appendix)

Element (atomic number)	Isotope ¹	Table I		Table II		
		Column 1	Column 2	Column 1	Column 2	
		† (μCi/ml)	(μCi/ml)	† (μCi/ml)	(μCi/ml)	
Thorium (90)	Th 234	5	6 × 10 ⁻⁸	5 × 10 ⁻⁸	3 × 10 ⁻⁸	3 × 10 ⁻⁸
	Th 230	I	3 × 10 ⁻⁸	5 × 10 ⁻⁸	1 × 10 ⁻⁸	2 × 10 ⁻⁸
Thulium (69)	Tm 170	5	4 × 10 ⁻⁸	1 × 10 ⁻⁸	1 × 10 ⁻⁸	3 × 10 ⁻⁸
	Tm 171	I	3 × 10 ⁻⁸	1 × 10 ⁻⁸	1 × 10 ⁻⁸	5 × 10 ⁻⁸
Tin (50)	Sn 113	5	1 × 10 ⁻⁷	1 × 10 ⁻⁷	4 × 10 ⁻⁸	5 × 10 ⁻⁸
	Sn 115	I	2 × 10 ⁻⁷	1 × 10 ⁻⁷	6 × 10 ⁻⁸	5 × 10 ⁻⁸
	Sn 117	5	4 × 10 ⁻⁷	3 × 10 ⁻⁷	1 × 10 ⁻⁷	9 × 10 ⁻⁸
	Sn 119	I	5 × 10 ⁻⁷	2 × 10 ⁻⁷	2 × 10 ⁻⁷	6 × 10 ⁻⁸
Tungsten (Wolfram) (74)	W 181	5	1 × 10 ⁻⁷	5 × 10 ⁻⁸	4 × 10 ⁻⁸	3 × 10 ⁻⁸
	W 182	I	2 × 10 ⁻⁷	1 × 10 ⁻⁷	6 × 10 ⁻⁸	4 × 10 ⁻⁸
	W 183	5	1 × 10 ⁻⁷	4 × 10 ⁻⁸	3 × 10 ⁻⁸	1 × 10 ⁻⁸
	W 184	I	1 × 10 ⁻⁷	2 × 10 ⁻⁸	4 × 10 ⁻⁸	1 × 10 ⁻⁸
Uranium (92)	U 230	5	6 × 10 ⁻¹⁰	3 × 10 ⁻¹⁰	1 × 10 ⁻¹¹	5 × 10 ⁻¹¹
	U 232	I	1 × 10 ⁻¹⁰	1 × 10 ⁻¹⁰	4 × 10 ⁻¹¹	5 × 10 ⁻¹¹
	U 233	5	3 × 10 ⁻¹¹	6 × 10 ⁻¹¹	3 × 10 ⁻¹¹	3 × 10 ⁻¹¹
	U 234	I	3 × 10 ⁻¹¹	9 × 10 ⁻¹¹	2 × 10 ⁻¹¹	3 × 10 ⁻¹¹
	U 235	5 ⁴	1 × 10 ⁻¹⁰	9 × 10 ⁻¹¹	4 × 10 ⁻¹¹	3 × 10 ⁻¹¹
	U 236	I	6 × 10 ⁻¹¹	6 × 10 ⁻¹¹	2 × 10 ⁻¹¹	3 × 10 ⁻¹¹
	U 238	5 ⁴	1 × 10 ⁻¹⁰	1 × 10 ⁻¹⁰	4 × 10 ⁻¹¹	3 × 10 ⁻¹¹
	U 239	I	7 × 10 ⁻¹¹	1 × 10 ⁻¹⁰	3 × 10 ⁻¹¹	4 × 10 ⁻¹¹
	U 240	I	1 × 10 ⁻¹⁰	1 × 10 ⁻¹⁰	5 × 10 ⁻¹¹	4 × 10 ⁻¹¹
	U 241	I	2 × 10 ⁻¹⁰	1 × 10 ⁻¹⁰	6 × 10 ⁻¹¹	3 × 10 ⁻¹¹
	U 242	I	3 × 10 ⁻¹⁰	1 × 10 ⁻¹⁰	6 × 10 ⁻¹¹	3 × 10 ⁻¹¹
	U-natural	5 ⁴	1 × 10 ⁻¹⁰	1 × 10 ⁻¹⁰	3 × 10 ⁻¹¹	3 × 10 ⁻¹¹
Vanadium (23)	V 46	5	1 × 10 ⁻¹⁰	1 × 10 ⁻¹⁰	5 × 10 ⁻¹¹	3 × 10 ⁻¹¹
	V 48	I	2 × 10 ⁻¹⁰	9 × 10 ⁻¹¹	6 × 10 ⁻¹¹	3 × 10 ⁻¹¹
Xenon (54)	Xe 121m	Sub	6 × 10 ⁻⁸	6 × 10 ⁻⁸	3 × 10 ⁻⁸	3 × 10 ⁻⁸
	Xe 133	Sub	2 × 10 ⁻⁸	4 × 10 ⁻⁸	4 × 10 ⁻⁸	4 × 10 ⁻⁸
	Xe 133m	Sub	1 × 10 ⁻⁸	3 × 10 ⁻⁸	3 × 10 ⁻⁸	3 × 10 ⁻⁸
	Xe 135	Sub	1 × 10 ⁻⁸	3 × 10 ⁻⁸	3 × 10 ⁻⁸	3 × 10 ⁻⁸
Ytterbium (70)	Yb 173	5	4 × 10 ⁻⁸	1 × 10 ⁻⁸	1 × 10 ⁻⁸	1 × 10 ⁻⁸
	Yb 175	I	7 × 10 ⁻⁷	3 × 10 ⁻⁷	2 × 10 ⁻⁷	1 × 10 ⁻⁷
Yttrium (39)	Y 90	5	6 × 10 ⁻⁷	3 × 10 ⁻⁷	2 × 10 ⁻⁷	1 × 10 ⁻⁷
	Y 91m	I	1 × 10 ⁻⁷	6 × 10 ⁻⁸	4 × 10 ⁻⁸	2 × 10 ⁻⁸
	Y 91	5	1 × 10 ⁻⁷	6 × 10 ⁻⁸	3 × 10 ⁻⁸	2 × 10 ⁻⁸
	Y 92	I	2 × 10 ⁻⁷	1 × 10 ⁻⁷	6 × 10 ⁻⁸	3 × 10 ⁻⁸
	Y 93	I	3 × 10 ⁻⁷	1 × 10 ⁻⁷	6 × 10 ⁻⁸	3 × 10 ⁻⁸
	Y 94	I	4 × 10 ⁻⁷	6 × 10 ⁻⁸	1 × 10 ⁻⁸	3 × 10 ⁻⁸
	Y 95	I	4 × 10 ⁻⁷	6 × 10 ⁻⁸	1 × 10 ⁻⁸	3 × 10 ⁻⁸
	Y 96	I	3 × 10 ⁻⁷	2 × 10 ⁻⁷	1 × 10 ⁻⁸	6 × 10 ⁻⁸

APPENDIX B
Concentrations in Air and Water Above Natural Background—Continued

Element (atomic number)	Isotope ¹	Table I		Table II	
		Column 1	Column 2	Column 1	Column 2
		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)	Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)
Zinc (30)	Zn 65	1 × 10 ⁻⁷	3 × 10 ⁻³	4 × 10 ⁻⁸	1 × 10 ⁻⁴
		6 × 10 ⁻⁸	3 × 10 ⁻³	2 × 10 ⁻⁸	2 × 10 ⁻⁴
	Zn 69m	4 × 10 ⁻⁷	2 × 10 ⁻³	1 × 10 ⁻⁸	7 × 10 ⁻⁴
		3 × 10 ⁻⁷	2 × 10 ⁻³	1 × 10 ⁻⁸	6 × 10 ⁻⁴
	In 69	7 × 10 ⁻⁴	3 × 10 ⁻³	2 × 10 ⁻⁷	2 × 10 ⁻³
Zirconium (40)	Zr 93	1 × 10 ⁻⁷	2 × 10 ⁻³	4 × 10 ⁻⁸	8 × 10 ⁻⁴
		3 × 10 ⁻⁷	2 × 10 ⁻³	1 × 10 ⁻⁸	8 × 10 ⁻⁴
	Zr 93	1 × 10 ⁻⁷	2 × 10 ⁻³	4 × 10 ⁻⁸	6 × 10 ⁻⁴
		3 × 10 ⁻⁷	2 × 10 ⁻³	1 × 10 ⁻⁸	6 × 10 ⁻⁴
	Zr 97	1 × 10 ⁻⁷	5 × 10 ⁻³	4 × 10 ⁻⁸	2 × 10 ⁻³
	9 × 10 ⁻⁸	5 × 10 ⁻³	2 × 10 ⁻⁸	2 × 10 ⁻³	
	Sub	1 × 10 ⁻⁴		3 × 10 ⁻⁴	
Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours.					
Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours.		2 × 10 ⁻⁴	9 × 10 ⁻³	1 × 10 ⁻¹⁰	3 × 10 ⁻⁴
Any single radionuclide not listed above, which decays by alpha emission or spontaneous fission.		6 × 10 ⁻¹³	4 × 10 ⁻³	2 × 10 ⁻¹⁴	3 × 10 ⁻⁴

¹Source (S), insoluble (I).
²"Sub" means that values given are for submersion in a semispherical infinite cloud of airborne material.

* These radon concentrations are appropriate for protection from radon-222 combined with its short-lived daughters. Alternatively, the value in Table I may be replaced by one-third (1/3) "working level." (A "working level" is defined as any combination of short-lived radon-222 daughters, polonium-218, lead-214, bismuth-214 and polonium-214 in one liter of air, without regard to the degree of equilibrium, that will result in the ultimate emission of 1.3 × 10⁵ MeV of alpha particle energy.) The Table II value may be replaced by one-thirtieth (1/30) of a "working level." The limit on radon-222 concentrations in restricted areas may be based on an annual average.

14. For soluble mixture of U-238, U-234 and U-235 in air chemical toxicity may be the limiting factor. If the percent by weight (enrichment) of U-235 is less than 5, the concentration value for a 40-hour workweek, Table I, is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 2 × 10⁻² SA $\mu\text{Ci-hr/ml}$, where SA is the specific activity of the uranium inhaled. The concentration value for Table II is 0.007 milligrams uranium per cubic meter of air. The specific activity for natural uranium is 6.77 × 10⁻² curies per gram U. The specific activity for other mixtures of U-238, U-234 and U-235, if not known, shall be:
SA = 2.6 × 10⁻¹ curies/gram U $\frac{U\text{-depleted}}{U\text{-enriched}}$
SA = (0.4 + 0.38 E + 0.0056 E²) 10⁻⁴ E > 0.72
where E is the percentage by weight of U-235 expressed as percent.

* Amended 37 FR 23319.
** Amended 39 FR 23990; footnote redesignated 40 FR 50704.
*** Amended 40 FR 50704.
† Amended 38 FR 29314.
‡ Amended 39 FR 25463; redesignated 40 FR 50704.

NOTE TO APPENDIX B

NOTE: In any case where there is a mixture in air or water of more than one radionuclide, the limiting values for purposes of this Appendix should be determined as follows:

1. If the identity and concentration of each radionuclide in the mixture are known, the limiting values should be derived as follows: Determine, for each radionuclide in the mixture, the ratio between the quantity present in the mixture and the limit otherwise established in Appendix B for the specific radionuclide when not in a mixture. The sum of such ratios for all the radionuclides in the mixture may not exceed "1" (i.e., "unity").

EXAMPLE: If radionuclides A, B, and C are present in concentrations C_A, C_B, and C_C, and if the applicable MPC's are MPC_A, MPC_B, and MPC_C respectively, then the concentrations shall be limited so that the following relationship exists:

C_A/MPC_A + C_B/MPC_B + C_C/MPC_C ≤ 1

2. If either the identity or the concentration of any radionuclide in the mixture is not known, the limiting value for purposes of Appendix B shall be:

- a. For purposes of Table I, Col. 1—6 × 10⁻⁴
b. For purposes of Table I, Col. 2—4 × 10⁻⁴
c. For purposes of Table II, Col. 1—2 × 10⁻⁴
d. For purposes of Table II, Col. 2—3 × 10⁻⁴

3. If any of the conditions specified below are met, the corresponding values specified below may be used in lieu of those specified in paragraph 2 above.

a. If the identity of each radionuclide in the mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the concentration limit for the mixture is the limit specified in Appendix "B" for the radionuclide in the mixture having the lowest concentration limit; or

b. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in Appendix "B" are not present in the mixture, the concentration limit for the mixture is the lowest concentration limit specified in Appendix "B" for any radionuclide which is not known to be absent from the mixture; or

25 FR 10394
30 FR 15607
30 FR 15808

30 FR 10394
30 FR 15607
30 FR 15808

Table with 4 columns: Element (atomic number) and isotopes, Table I Column 1 Air (uCi/ml), Table I Column 2 Water (uCi/ml), Table II Column 1 Air (uCi/ml), Table II Column 2 Water (uCi/ml). Rows include conditions for Sr 90, Ra 226, Th 230, Pa 231, Pu 238, 239, 240, 241, 242, 244, Cm 244, 246, 248, Cf 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400.

30 FR 15808

40 FR 50704
30 FR 73990
36 FR 10046

4. If a mixture of radionuclides consists of uranium and its daughters in ore dust prior to chemical separation of the uranium from the ore, the values specified below may be used for uranium and its daughters through radium-226, instead of those from paragraphs 1, 2, or 3 above.

- a. For purposes of Table I, Col. 1—1 × 10⁻⁴ uCi/ml gross alpha activity; or 5 × 10⁻⁴ uCi/ml natural uranium; or 70 micrograms per cubic meter of air natural uranium.
b. For purposes of Table II, Col. 1—5 × 10⁻⁴ uCi/ml gross alpha activity; or 2 × 10⁻⁴ uCi/ml natural uranium; or 8 micrograms per cubic meter of air natural uranium.

5. For purposes of this Note, a radionuclide may be considered as not present in a mixture if (a) the ratio of the concentration of that radionuclide in the mixture (C_i) to the concentration limit for that radionuclide specified in Table II of Appendix B (MPC_i) does not exceed 1/10

(i.e. C_i/MPC_i ≤ 1/10) and (b) the sum of such ratios for all the radionuclides considered as not present in the mixture does not exceed 1/10

(i.e. C₁/MPC₁ + C₂/MPC₂ + ... ≤ 1/10)

PART 20 • STANDARDS FOR PROTECTION AGAINST RADIATION

APPENDIX C

Material	Microcuries
Americium-241	01
Antimony-122	100
Antimony-124	10
Antimony-126	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-116	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-136	10
Cesium-137	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-153 9.3 h	100
Europium-152 12 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-136	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lucretium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-50	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10

Material	Microcuries
Osmium-191m ¹	100
Osmium-191	100
Osmium-198	100
Palladium-103	100
Palladium-106	100
Phosphorus-32	10
Platinum-181	100
Platinum-189m	100
Platinum-192	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	01
Poonium-210	0.1
Potassium-42	10
Praseodymium-143	100
Praseodymium-145	100
Promethium-147	10
Promethium-160	10
Radium-226	01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-106	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-100	10
Ruthenium-106	10
Ruthenium-108	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-76	10
Silicon-31	100
Silver-106	10
Silver-110m	1
Silver-111	100
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
**Thorium (natural) ¹	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
**Uranium (natural) ²	100
Uranium-233	01
Uranium-234 Uranium-235	01
Vanadium-46	10
Xenon-133m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-176	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10

Any alpha emitting radionuclide not listed above or mixture of alpha emitters of unknown composition 01

Any radionuclide other than alpha emitting radionuclides not listed above or mixture of beta emitters of unknown composition... 1

Note.—For purposes of § 20.203, where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows. Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e., "unity").

¹ Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.
² Based on alpha disintegration rate of U-238, U-234, and U-235.
 * Amended 36 FR 16898.
 ** Amended 39 FR 23990.

PART 20 • STANDARDS FOR PROTECTION AGAINST RADIATION

APPENDIX D — UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICES

50 FR 46630

	Addresses	Telephone (24 hours)
Region I: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.	USNRC, 631 Park Avenue, King of Prussia, PA 19406	(215) 337-5000 (FTS) 488-1000
Region II: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, and West Virginia.	USNRC, 101 Marietta Street, NW, Suite 2900, Atlanta, GA 30323	(404) 331-4503 (FTS) 242-4503
Region III: Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.	USNRC, 796 Roosevelt Road, Glen Ellyn, IL 60137	(312) 790-5500 (FTS) 388-5500
Region IV: Arkansas, Colorado, Idaho, Kansas, Louisiana, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, Utah, and Wyoming.	USNRC, 611 Ryan Plaza Drive, Suite 1000, Arlington, TX 76011	(817) 880-8100 (FTS) 726-8100
Region IV: Field Office	USNRC, Region IV Uranium Recovery Field Office, 730 Simms Street, P.O. Box 25325, Denver, CO 80225	(303) 234-7232 (FTS) 234-7232
Region V: Alaska, Arizona, California, Hawaii, Nevada, Oregon, Pacific Trust Territories, and Washington.	USNRC, 1450 Mare Lane, Suite 210, Walnut Creek, CA 94596	(415) 943-3700 (FTS) 463-3700

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109564

12 SEP 1988

13 SEP 1988

OFFICIAL RECORD COPY

Application for Byproduct Material License to NRC
Eisai Research Institute of Boston, Inc.

Attachment VI

Item 11. Waste Management

The radioactive waste disposal procedures are outlined in detail in appendix 4, pages 31 through 35 of the RADIATION SAFETY GUIDE, Attachment V. of this application packet.

All collected waste for off-site shipment will be transported to the Low Level Radioactive Waste Disposal Site in Richland, Washington by NDL Organization, Inc., P.O. Box 791, Peekskill, N.Y., 10566.

All solid waste that are to be "stored until they decay to background," will be stored according to the procedures described on page 32 of the RADIATION SAFETY GUIDE. Five gallon steel barrels will be used for each lot of disposed solid waste. The barrels will be stored in the cabinet under the radioactive hood designated on the floor plan of the research facility (Item 9 of this application). The steel cabinet will be lined with lead shields $1/16^{\text{th}}$ inch thick on all walls and doors for extra protection.

The remainder of the radioactive waste will be collected according to the procedures outlined on page 32 of the RADIATION SAFETY GUIDE and stored in five gallon steel barrels. The five gallon barrels will also be stored in the cabinet under the radioactive hood until the pickup is made by the NDL Organization for transport to the Richland, Washington site.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: _____
STATUS CODE: 3
FEE CATEGORY: _____
EXP. DATE: 0
FEE COMMENTS: _____
.....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: EISAI RESEARCH INST. OF BOSTON, INC
RECEIVED DATE: 880912
DOCKET NO: 3030804
CONTROL NO.: 109564
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED

AMOUNT: \$700.00
CHECK NO.: 385

3. COMMENTS

SIGNED _____
DATE 9-23-88

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1.5)

1. FEE CATEGORY AND AMOUNT: 3M \$700

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT _____
RENEWAL _____
LICENSE

3. OTHER _____

SIGNED _____
DATE 10/27/88