State of Rhode Island and Providence Plantations

EXECUTIVE CHAMBER, PROVIDENCE

J. Joseph Garrahy
Governor

May 25, 1979

The Honorable Joseph M. Hendrie
Chairman
United States Nuclear Regulatory
Commission
Washington, DC 20555

Dear Mr. Chairman:

It is requested that the United States Nuclear Regulatory Commission enter into an agreement with the State of Rhode Island to provide for discontinuance of certain Commission authority and responsibility fo[illegible]he regulation of sources of ionizing radiation and t[illegible]assumption thereof by this State.

Section 23-1.3-7 of the General Laws of Rhode Island authorizes me, as Governor of Rhode Island, on behalf of this State, to enter into an agreement of this type.

The Rhode Island Department of Health is designated in Section 23-1.3-2 of the General Laws of Rhode Island as the agency responsible for administering and enforcing regulations for the control of ionizing radiation in the State of Rhode Island.

I hereby certify that the State of Rhode Island has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State desires to assume regulatory responsibility for such materials. I also certify that there is no by-product material as defined in Section 11e(2) of Atomic Energy Act of 1954, as amended, within the State and that there is no activity within the State resulting in the production of such by-product material.

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The following documents are enclosed in support of this request: (1) a copy of the proposed agreement; (2) Rhode Island's Radiation Control Program; and (3) Rhode Island's Rules and Regulations for the Control of Radiation.

We would like to execute the agreement as soon as possible, and we propose that the effective date for the assumption of regulatory authority by the State of Rhode Island be October 1, 1979.

With best wishes, I am,

Sincerely,

J. Joseph Garrahy
GOVERNOR

Enclosure

AGREEMENT
BETWEEN THE
UNITED STATES NUCLEAR REGULATORY COMMISSION
AND THE
STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
FOR
DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY
AND
RESPONSIBILITY WITHIN THE STATE PURSUANT TO
SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

WHEREAS, The United States Nuclear Regulatory Commission (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act), to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to by-product materials as defined in sections 11e.(1) and (2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and

WHEREAS, The Governor of the State of Rhode Island and Providence Plantations is authorized under 23-1.3-7 of the General Laws of Rhode Island to enter into this Agreement with the Commission; and

WHEREAS, The Governor of the State of Rhode Island and Providence Plantations certified on , that the State of Rhode Island and Providence Plantations (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and

WHEREAS, The Governor of the State of Rhode Island and Providence Plantations certified on , that there is no byproduct material as defined in section 11e.(2) of the Act within the State and that there is no activity within the State resulting in the production of byproduct material as defined in section 11e.(2) of the Act; and

WHEREAS, The Commission found on , that the program of the State for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect the public health and safety; and

WHEREAS, The Commission found on , that there are no NRC licenses outstanding in the State for byproduct material as defined in section 11e.(2) of the Act or for any activity within the State resulting in the production of byproduct material as defined in section 11e.(2) of the Act; and

WHEREAS, The State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and

WHEREAS, The Commission and the State recognize the desirability of reciprocal recognition of licenses and exemptions from licensing of those materials subject to this Agreement; and

WHEREAS, The State and the Commission recognize that it will be necessary to consider amendments to this Agreement in the event that the State wishes to regulate byproduct material as defined in Section 11e.(2) of the Act and that it will be necessary to amend this Agreement in the event any activity resulting in the production of byproduct material as defined in section 11e.(2) of the act is found to exist within the State; and

WHEREAS, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

NOW, THEREFORE, It is hereby agreed between the Commission and the Governor of the State, acting in behalf of the State, as follows:

ARTICLE I

Subject to the exceptions provided in Articles II, III, and IV, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

A. Byproduct materials as defined in section 11e.(1) of the Act;

B. Source materials; and

C. Special nuclear materials in quantities not sufficient to form a critical mass.

ARTICLE II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of:

A. The construction and operation of any production or utilization facility;

B. The export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;

C. The disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission;

D. The disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission.

ARTICLE III

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

ARTICLE IV

This Agreement shall not affect the authority of the Commission under subsection 161 b. or i. of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material.

ARTICLE V

The Commission will use its best efforts to cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible. The State will use its best efforts to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of like materials. The State and the Commission will use their best efforts to keep each other informed of proposed changes in their respective rules and regulations and licensing, inspection and enforcement policies and criteria, and to obtain the comments and assistance of the other party thereon.

Article VI

The Commission and the State agree that it is desirable to provide for reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any Agreement State. Accordingly, the Commission and the State agree to use their best efforts to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

ARTICLE VII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend all or part of this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect the public health and safety or (2) the State has not complied with one or more of the requirements of section 274 of the Act. The Commission shall periodically review this Agreement and actions taken by the State under this Agreement to ensure compliance with section 274 of the Act.

ARTICLE VIII

This Agreement shall become effective on and shall remain in effect unless and until such time as it is terminated pursuant to Article VII.

Done at Providence, State of Rhode Island, in triplicate, this day of

FOR THE UNITED STATES NUCLEAR REGULATORY COMMISSION

_____

FOR THE STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

_____

J. Joseph Garrahy, Governor

RULES and REGULATIONS for the CONTROL of RADIATION

Radiation Control Agency

Division of Occupational Health

Department of Health

Rhode Island

1979 FEBRUARY

RHODE ISLAND REGULATIONS FOR CONTROL OF RADIATION

These Rhode Island Regulations for the Control of Radiation were adopted in accordance with the Rhode Island Radiation Control Act, Title 23, Chapter 1.3 of the General Laws and the Administrative Procedures Act, Title 42, Chapter 35 of the General Laws. They are generally compatible with similar regulations of other states and with those of the U.S. Department of Health, Education and Welfare and the U.S. Nuclear Regulatory Commission.

These regulations presently apply to all x-ray facilities and certain providers of services to x-ray facilities. Part C, which requires the licensing of radioactive material, will become effective upon the date of an agreement between the State of Rhode Island and the U.S. Nuclear Regulatory Commission under the provisions of Section 274 of the Atomic Energy Act of 1954, as amended.

NO X-RAY FACILITY OR APPLICABLE SERVICE IS AUTHORIZED TO OPERATE IN RHODE ISLAND WITHOUT A CURRENT CERTIFICATE OF REGISTRATION.

X-ray facilities will receive advance notice of initial inspection in order to facilitate the conduct of the inspection. No prior notice will ordinarily be given for follow-up inspections, inspections in response to complaints, other inspections subsequent to the initial inspection of a facility or inspections of radioactive material licenses.

The format of these regulations was designed for easy reference and for economy. Further amendments will be issued as new Parts or substitute pages. Normally only one copy will be furnished to each registrant or licensee; therefore, these regulations and future amendments to them may be duplicated in whole or in part without permission.

Communications related to these regulations should be addressed to the State Radiation Control Agency as follows:

Division of Occupational Health and Radiation Control
Rhode Island Department of Health
Cannon Building
Davis Street
Providence, Rhode Island 02908

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RHODE ISLAND RULES AND REGULATIONS

FOR THE

CONTROL OF RADIATION

PART A

GENERAL PROVISIONS OF THE REGULATIONS;
STANDARDS FOR PROTECTION AGAINST RADIATION;
NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

Adopted 5 February 1979

PART A

GENERAL PROVISIONS OF THE REGULATIONS; STANDARDS FOR PROTECTION AGAINST RADIATION; NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

A.1 GENERAL PROVISIONS

A.1.1 Purpose and Scope.

(a) This part establishes generally applicable provisions of these regulations, including standards for protection against radiation hazards, notices, instructions and reports to workers, and inspections. Except as otherwise specifically provided, this part applies to all licensees and registrants, provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. The rules and regulations set forth herein, as they relate to radioactive materials subject to regulation by the U.S. Nuclear Regulatory Commission, shall be effective on the effective date of an agreement between the State of Rhode Island and the U.S. Nuclear Regulatory Commission under provisions of Section 274 of the Atomic Energy Act of 1954, as amended (73 Stat. 689). The rules and regulations set forth herein as they relate to all other sources of radiation shall be effective on June 2, 1978.

(b) In addition to complying with the requirements set forth in this part, every reasonable effort should be made to maintain radiation exposures, and releases of radioactive material 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 socio-economic considerations, and in relation to the utilization of ionizing radiation in the public interest.

(c) Except as specifically provided in other parts of these regulations, nothing in Subparts A.2, A.3, A.4, A.5, A.6 and the Appendices to part A shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or therapy.

A.1.2 Units of Radiation Dose.

(a) "Dose" as used in these regulations shall mean absorbed dose or dose equivalent, as appropriate. "Absorbed dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. "Dose equivalent" is a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. See paragraphs (b) and (d).

(b) The "rad" is the special unit of absorbed dose. One rad equals one hundreth of a joule per kilogram of material; for example, if tissue is the material of interest, then 1 rad equals 100 ergs per gram of tissue.

(c) "Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58×10^{-4} coulombs/kilogram of air.

(d) The "rem" is a measure of the dose of any radiation to body tissue in terms of its estimated biological effect relative to a dose received from an exposure to 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 purposes of these regulations, any of the following is considered to be equivalent to a dose of one rem:

(1) An exposure of 1 R due to X-, or gamma radiation;

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

(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 absorbed dose in rads, as provided in subparagraph (3) of this paragraph, one rem of neutron radiation may, for purposes of these regulations, 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 per sec.)
Thermal	970×10^6	670
0.0001	720×10^6	500
0.005	820×10^6	570
0.02	400×10^6	280
0.1	120×10^6	80
0.5	43×10^6	30
1.0	26×10^6	18
2.5	29×10^6	20
5.0	26×10^6	18
7.5	24×10^6	17
10.0	24×10^6	17
10 to 30	14×10^6	10

A.1.3 Units of Radioactivity. Radioactivity shall be measured in terms of curies. A curie is that quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegrations per second or 2.2×10^{12} disintegrations per minute. A commonly used submultiple of the curie is the microcurie (μCi). One μCi = 1×10^{-6} Ci = 3.7×10^4 dps = 2.2×10^6 dpm.

A.1.4 Exemptions.

(a) General Provision. The Agency may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(b) Carriers. Common and contract carriers, freight forwarders, and warehousemen, who are subject to the rules and regulations of the U.S. Department of Transportation or the U.S. Postal Service (39 CFR Parts 14 & 15), are exempt from these regulations to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto. Private carriers who are subject to the rules and regulations of the U.S. Department of Transportation are exempted from these regulations to the extent that they transport sources of radiation. Common, contract, and private carriers who are not subject to the rules and regulations of the U.S. Department of Transportation or the U.S. Postal Service are subject to applicable sections of these regulations.

(c) U.S. Energy Research and Development Administration contractors and U.S. Nuclear Regulatory Commission contractors. Any U.S. Energy Research and Development Administration contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) Prime contractors performing work for the Energy Research and Development Administration at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) Prime contractors of the Energy Research and Development Administration performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

(3) Prime contractors of the Energy Research and Development Administration using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

(4) Any other prime contractor or subcontractor of the Energy Research and Development Administration or of the Nuclear Regulatory Commission when the State and the Nuclear Regulatory Commission jointly determine,
(i) that, the exemption of the prime contractor or subcontractor is authorized by law, and
(ii) that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

A.1.5 Records. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. All records required by these regulations shall be maintained indefinitely unless otherwise specified in these regulations.

A.1.6 Inspections.

(a) Each licensee and registrant shall afford the Agency at all reasonable times the opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored, and the cooperation and assistance of the registrant or licensee, or his staff, if needed.

(b) Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to these regulations.

A.1.7 Tests. Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

(a) Sources of radiation;

(b) Facilities wherein sources of radiation are used or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

A.1.8 Additional Requirements. The Agency may, by rule, regulations, or order, impose upon any licensee or registrant such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

A.1.9 Violations. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a misdemeanor and upon conviction, may be punished by fine or imprisonment or both, as provided by law.

A.1.10 Communications. All communications and reports concerning these regulations, and applications filed thereunder, should be addressed to the Agency at its office located at:

Division of Occupational Health
and Radiation Control
206 Cannon Building
75 Davis Street
Providence, Rhode Island 02908

A.2 PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS

A.2.1 Exposure of Individuals to Radiation in Controlled Areas.

(a) Except as provided in paragraph (b) of this section, no licensee or registrant shall possess, use, receive, or transfer sources of radiation in such a manner as to cause any individual in a controlled area to receive in any period of one calendar quarter from all sources of radiation in the licensee's or registrant's possession a dose in excess of the limits 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 3/4
3. Skin of whole body	7 1/2

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

(1) During any calendar quarter the dose to the whole body from sources of radiation in the licensee's or registrant's possession 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 or registrant has determined the individual's accumulated occupational dose to the whole body on Agency Form RCA-2 or on a clear and legible record containing all the information required in that form, and has otherwise complied with the requirements of Section A.2.2. 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.

A.2.2 Determination of Accumulated Dose

(a) This section contains requirements which must be satisfied by licensees or registrants who propose, pursuant to A.2.1 (b), to permit individuals in a controlled area to receive exposure to radiation in excess of the limits specified in A.2.1 (a).

(b) Before permitting any individual in a controlled area to receive exposure to radiation in excess of the limits specified in A.2.1 (a), each licensee or registrant shall:

(1) Obtain a certificate on Agency Form RCA-2 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

A.2.2 (b) (2)

(2) Calculate on Agency Form RCA-2 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 A.2.1 (b).

(c) (1) In the preparation of Agency Form RCA-2 or a clear and legible record containing all the information required in that form, the licensee or registrant shall make a reasonable effort to obtain reports of the individual's previous accumulated occupational dose. For each period for which the licensee or registrant obtains such reports, he shall use the dose shown in the report in preparing the form. In any case where a licensee or registrant 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 dose in rems for calendar quarters prior to January 1, 1961	Column 2 Assumed dose in rems for calendar quarters beginning on or after January 1, 1961
Whole body, gonads, active blood-forming organs, head & trunk, lens of eye	3 3/4	1 1/4

(2) The licensee or registrant shall retain and preserve records used in preparing Agency Form RCA-2 until the Agency 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 A.2.1 (b), the excess may be disregarded.

A.2.3 Exposure of Individuals to Concentrations of Radioactive Materials in Air in Restricted Areas.

(a) No licensee shall possess, use, or transfer radioactive 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 A, Table I, Column 1. [1,2,3] 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 intake[4,5] 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 A, Table I, Column 1.

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[1]Since 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 in H 3 S in Appendix A, Table 1, Column 1 for 40 hours per week for 13 weeks.

[2]For 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 A.2.1. These nuclides shall be subject to the precautionary procedures required by A.2.3 (b).

[3]Multiply the concentration values specified in Appendix A, Table I, Column 1, by 6.3×10^8 ml to obtain the quarterly quantity limit. Multiply the concentration value specified in Appendix A, Table I, Column 1, by 2.5×10^9 ml to obtain the annual quantity limit for Rn-222.

[4]Significant 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 A.2.3 (a) (1) has been exceeded.

[5]Regulatory 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 Radiation Control Agency, 206 Cannon Building, Davis Street, Providence, RI 02908, upon written request.

A.2.3 (a) (2)

(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 A, 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 intake[4] does not exceed that which would result from inhaling such material at the limits specified in Appendix A, Table I, Column 1 and footnote 4 thereto.

(3) For purposes of determining compliance with the requirements of A.2.3 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 A.2.3 (c). When 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 A, 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 A.3.3 (d) (2).

(2) When it is impracticable to apply process or other engineering controls to limit concentrations of radioactive material in air below those defined in A.3.3 (d) (2), 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

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[4] Significant 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 A.2.3 (a) (1) has been exceeded.

at the uniform concentrations specified in Appendix A, 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 A.2.3 (b) (2), the licensee may make allowance for such use in estimating exposures of individuals to such materials provided that such equipment is used as stipulated in Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection."[6]

(d) Notwithstanding the provisions of A.2.3 (b) and (c), the Agency may impose further restrictions:

(1) On the extent to which a licensee may make allowance for use of respirators in lieu of provision of process, containment, ventilation, or other engineering controls, if application of such controls is found to be practicable; and

(2) as might be necessary to assure that the respiratory protective program of the licensee is adequate in limiting exposures of personnel to airborne radioactive materials.

(e) The licensee shall notify, in writing, the Agency at least 30 days before the date that respiratory protective equipment is first used under the provisions of this section.

(f) A licensee who was authorized to make allowance for use of respiratory protective equipment prior to (the effective date of this regulation) shall bring his respiratory protective program into conformance with the requirements of A.2.3 (c) within one year of that date, and is exempt from the requirements of A.2.3 (e).

A.2.4 Exposure of Minors.

(a) No licensee or registrant shall possess, use, or transfer sources of radiation in such a manner as to cause any individual within a controlled area, who is under 18 years of age, to receive in any period of one calendar quarter from all sources of radiation in such licensee's or registrant's possession a dose in excess of 10 percent of the limits specified in the table in A.2.1 (a).

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[6]Single copies of Regulatory Guide 8.15 are available from the Radiation Control Agency, 206 Cannon Building, Davis Street, Providence, RI 02908, upon written request.

A.2.4 (b)

(b) No licensee shall possess, use, or transfer radioactive material in such a manner as to cause any individual within a controlled area, who is under 18 years of age, to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Appendix A, 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 A.2.3 (b) (2) and A.2.3 (c) shall apply to exposures subject to A.2.4 (b) except that the references in A.2.3 (b) (2) and A.2.3 (c) to Appendix A, Table I, Column 1 shall be deemed to be references to Appendix A, Table II, Column 1.

A.2.5 Permissible Levels of Radiation from External Sources in Uncontrolled Areas.[1]

(a) Except as authorized by the Agency pursuant to paragraph (b) of this section, no licensee or registrant shall possess, use, or transfer sources of radiation in such a manner as to create in any uncontrolled area from such 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.

(b) Any person may apply to the Agency for proposed limits upon levels of radiation in uncontrolled areas in excess of those specified in paragraph (a) of this section resulting from the applicant's possession or use of sources of radiation. Such applications should include information as to anticipated average radiation levels and anticipated occupancy times for each uncontrolled area involved. The Agency will approve the proposed limits if the applicant demonstrates to the satisfaction of the Agency 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.

A.2.6 Concentrations of Radioactive Materials in Effluents to Uncontrolled Areas.

(a) A licensee shall not possess, use, or transfer radioactive material so as to release to an uncontrolled area radioactive material in concentrations which exceed the limits specified in Appendix A, Table II of

[1] It is the intent of this section to limit radiation levels so that it is unlikely that individuals in unrestricted areas would receive a dose to the whole body in excess of 0.5 rem in any one year. If in specific instances, it is determined by the Agency that this intent is not met, the Agency may, pursuant to A.1.8 impose such additional requirements on the licensee or registrant as may be necessary to meet the intent.

this part, except as authorized pursuant to section A.4.2 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 Agency 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 uncontrolled 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 A, 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 concentrations of radioactive materials discharged in effluents to uncontrolled 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 chemical composition; physical characteristics, including suspended solids content in liquid effluents, and nature of gas or aerosol for air effluents; the hydrogen ion concentrations (pH) of liquid effluents; and the size range of particulates in effluents released into air.

(3) A description of the anticipated human occupancy in the uncontrolled area where the highest concentration of radioactive material from the effluent is expected. In the case of a river or stream, a description of water uses downstream from the point of release of the effluent is required. In the case of a body of water other than a river or stream, the Agency may require a more detailed description of the water uses.

(4) Information as to the highest concentration of each radionuclide in an uncontrolled area, including anticipated concentrations averaged over a period of one year, in air at any point of human occupancy; or 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 uncontrolled area and possible reconcentrations 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.

A.2.6 (d)

(d) For the purposes of this section, the concentration limits in Appendix A, Table II of this part shall apply at the boundary of the controlled 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 controlled 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 Agency 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 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 A, Table II of this part.

(f) The provisions of this section do not apply to disposal of radioactive material into sanitary sewerage systems, which is governed by A.4.3.

A.2.7 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 Agency may incorporate license provisions or issue an order requiring a licensee or registrant to make available to the individual appropriate bio-assay services and to furnish a copy of the reports of such services to the Agency.

A.3 PRECAUTIONARY PROCEDURES

A.3.1 Surveys.

(a) As used in this part, "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of 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 or registrant shall make or cause to be made such survey as may be necessary for him to comply with this part.

A.3.2 Personnel Monitoring.

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

(1) Each individual who enters a controlled 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 A.2.1 (a).

A.3.2 (a) (2)

(2) Each individual under 18 years of age who enters a controlled 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 A.2.1 (a).

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

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

(c) "Radiation area" means any area, accessible to individuals, in which there exists radiation 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 millirem.

(d) "High radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.

A.3.3 Caution Signs, Labels, and Signals.

(a) General. Except as otherwise authorized by the Agency, 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, as illustrated in Appendix C of this part. In addition to the content of signs and labels prescribed in this section, a licensee or registrant may provide on or near such signs and labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation.

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

CAUTION[2]

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[2]

HIGH RADIATION AREA

(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

[2]Or "Danger."

(ii) Equipped with a control device which shall energize a conspicuously 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 subparagraph (2) of this paragraph 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 above controls.

(5) Any licensee or registrant may apply to the Agency for approval of methods not included in subparagraphs (2) and (4) of this paragraph for controlling access to high radiation areas. The Agency will approve the proposed alternatives if the licensee or registrant demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area, and that the requirement of subparagraph (3) of this paragraph 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 radioactive source[1] 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 impossible 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 A.3.3 (c) (6) shall be established in such a way that no individual will be prevented from leaving the area.

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[1]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. A.3.3 (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.

A.3.3 (c) (6) (ii)

(ii) Be equipped with additional control devices such that upon failure of the entry control devices to function as required by A.3.3 (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 comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of A.3.3 (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 A.3.3 (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 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 A.3.3 (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 A.3.3 (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. Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[2]

AIRBORNE RADIOACTIVITY AREA

As used in this part, "airborne radioactivity area" means:

(1) Any room enclosure, or operating area in which airborne radioactive material exists in concentrations in excess of the amounts specified in Appendix A, Table I, Column I, of this part; or

(2) Any room, enclosure, or operating area in which airborne radioactive 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 A, Table I, Column I, of this part.

[2]Or "Danger."

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(e) Additional Requirements.

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

CAUTION[2]

RADIOACTIVE MATERIAL

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

CAUTION[2]

RADIOACTIVE MATERIAL

(f) Containers.

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

(2) A label required pursuant to subparagraph (1) of this paragraph shall bear the radiation caution symbol and the words:

CAUTION[2]

RADIOACTIVE MATERIAL

It shall also provide sufficient information[3] to permit individuals handling or using the containers, working in the vicinity thereof, to take precautions to avoid or minimize exposures.

(3) Notwithstanding the provisions of subparagraph (1) of this paragraph, labeling is not required:

(i) For containers that do not contain radioactive materials in quantities greater than the applicable quantities listed in Appendix B of this part;

(ii) For cortainers containing only natural uranium or thorium in quantities no greater than ten times the applicable quantities listed in Appendix B of this part;

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[2]Or "Danger."

[3]As appropriate, the information will include radiation levels, kinds of material, estimate of activity, date for which activity is estimated, etc.

(iii) For containers that do not contain radioactive materials in concentrations greater than the applicable concentrations listed in Column 2, Table I, Appendix A 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 accessible[4] 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; and

(vii) For manufacturing and process equipment such as piping and

(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.

(g) All radiation machines shall be labeled in a manner which cautions individuals that radiation is produced when the machine is being operated.

A.3.4 Exceptions from Posting Requirements. Notwithstanding the provisions of A.3.3:

(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 [illegible] level twelve inches from the surface of the source container [illegible]ing does not exceed five millirem per hour.

(b) 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 attented 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 this part, and;

(2) Such area or room is subject to the licensee's or registrant's control.

(c) Rooms or other a[illegible] hospitals are not required to be posted with caution signs, and [illegible]rol of entrance or access thereto pursuant to paragraph A.3.3 (c) is not required, because of the presence of patients containing radioactive 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.

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

A.3.4 (d)

(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.

A.3.5 Instruction of Personnel. Instructions required for individuals working in or frequenting any portion of a controlled area are specified in section A.6.3.

A.3.6 Storage of Sources of Radiation.

(a) Sources of radiation shall be secured against unauthorized removal from the place of storage.

(b) Sources of radiation in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant.

A.3.7 Procedures for Picking Up, Receiving, and Opening Packages.

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of the Type A quantities specified in A.3.7 (c) (1) shall:

(1) 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

(2) 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.

(b) 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.

(c) 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:

(1) Packages containing no more than the exempt quantity specified in the following table:

Table of Exempt and Type A Quantities

Transport Group	Exempt Quantity Limit (in millicuries)	Type A Quantity Limit (in curies)
I	0.01	0.001
II	0.1	0.050
III	1	3
IV	1	20
V	1	20
VI	1	1,000
VII	25,000	1,000
Special form	1	20

A.3.7 (c) (2)

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

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

(4) 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 A.3.7 (c) (1); and

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

(d) 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.

(e) If removable radioactive contamination in excess of 0.01 microcurie (22,200 disintegrations per minute) per 100 square centimeters of package surface is found on the external surfaces of the package, the licensee shall immediately notify, by 1) telephone and 2) telegraph, mailgram or facsimile, the final delivering carrier and the Agency.

(f) Each licensee, upon receipt of a package containing quantities of radioactive material in excess of the Type A quantities specified in A.3.7 (c) (1), 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. 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 1) telephone and 2) telegram, mailgram or facsimile, the final delivering carrier and the Agency.

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

A.4 WASTE DISPOSAL

A.4.1 General Requirement. No licensee shall dispose of any radioactive material except:

(a) By transfer to an authorized recipient as provided in part C, or

(b) As authorized pursuant to sections A.4.2, A.4.3, A.4.4, or A.2.6.

A.4.2 Method of Obtaining Approval of Proposed Disposal Procedures. Any person may apply to the Agency for approval of proposed procedures to dispose of radioactive material in a manner not otherwise authorized in this part. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and the levels of radioactivity involved, and the proposed manner and conditions of disposal. The application, where appropriate, 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.

The Agency will not approve any application for a license to receive radioactive material from other persons for disposal on land not owned by the State or Federal Government.

A.4.3 Disposal by Release into Sanitary Sewerage Systems. No licensee shall discharge radioactive material into a sanitary sewerage system unless:

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

(b) The quantity of any radioactive material released into the system by the licensee in any one day does not exceed the larger of subparagraphs (1) or (2) of this paragraph:

(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 not greater than the limits specified in Appendix A, Table I, Column 2, of this part; or

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

(c) The quantity of any 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 A, Table I, Column 2, of this part; and

(d) The gross quantity of radioactive material released into the sewerage system by the licensee does not exceed one curie per year;

(e) This section does not authorize disposal by septic tank or cesspool-type sewerage system.

Excreta from individuals undergoing medical diagnosis or therapy with radioactive materials shall be exempt from any limitations contained in A.4.3.

A.4.4 Disposal by Burial in Soil. No licensee shall dispose of radioactive material by burial in soil unless:

A.4.4 (a)

(a) The total quantity of radioactive materials buried at any one location and time does not exceed, at the time of burial, 1,000 times the amount specified in Appendix B of this part; and

(b) Burial is at a minimum depth of four feet; and

(c) Successive burials are separated by distances of at least six feet and not more than 12 burials are made in any one year.

A.4.5 Treatment or Disposal by Incineration. No licensee shall treat or dispose of licensed material by incineration except as specifically approved by the Agency pursuant to sections A.2.6 (b) and A.4.2.

A.5 RECORDS, REPORTS, AND NOTIFICATION

A.5.1 Records of Surveys, Radiation Monitoring, and Disposal.

(a) Each licensee or registrant shall maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under section A.3.2 of this part. Such records shall be kept on Agency Form RCA-3 in accordance with the instructions contained in that form, or on clear and legible records containing all the information required by Agency Form RCA-3. The doses entered on the forms or records shall be for periods of time not exceeding one calendar quarter.

(b) Each licensee or registrant shall maintain records in the same units used in this part, showing the results of surveys required by A.3.1 (b), monitoring required by A.3.7 (c) and A.3.7 (f) and disposals made under A.4.2, A.4.3, and A.4.4.

(c) Records of individual radiation exposure which must be maintained pursuant to the provisions of paragraph (a) of this section and records of bioassays, including the results of whole body counting examinations, made pursuant to A.2.7, shall be preserved indefinitely, or until such time as authorized by the Agency. Records which must be maintained pursuant to this part may be maintained in the form of microfilm.

(d) 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 Agency authorizes their disposition:

(1) Records of the results of surveys to determine compliance with paragraph A.2.3 (a);

(2) In the absence of personnel monitoring data, records of the results of surveys to determine external radiation dose; and

(3) Records of the results of surveys used to evaluate the release of radioactive effluents to the environment.

(e) Records of disposal of licensed material made pursuant to section A.4.2, A.4.3, or A.4.4 shall be maintained until the Agency authorizes their disposition.

A.5.1 (f)

(f) 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 Agency regulations.

(g) The Agency may grant specific exemptions to the record retention period requirements of this section.

(h) The discontinuance of a radiation installation, or curtailment of certain activities, does not relieve the licensee or registrant of responsibility for retaining all records required by this section. A licensee or registrant may, however, request the Agency to accept such records. The acceptance of the records by the Agency relieves the licensee or registrant of subsequent responsibility only in respect to their preservation as required by this section.

A.5.2 Reports of Theft or Loss of Sources of Radiation.

(a) Each licensee or registrant shall report by 1) telephone and 2) telegram, mailgram or facsimile to the Agency the theft or loss of any source of radiation immediately after such occurrence becomes known.

(b) Each licensee who is required to make a report pursuant to paragraph (a) of this section shall, within thirty (30) days after he learns of the loss or theft, make a report in writing to the Agency, setting forth 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 individuals, 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.

A.5.3 Notification of Incidents.

(a) Immediate Notification. Each licensee or registrant shall immediately notify the Agency by telephone and telegraph of any incident involving any source of radiation possessed by him and which may have caused or threatens to cause:

(1) A dose to the whole body of any individual of 25 rems or more of radiation; a dose to the skin of the whole body of any individual of 150 rems or more of radiation; or a dose to the feet, ankles, hands, or forearms of any individual of 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 5000 times the limits specified for such materials in Appendix A, Table II, 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 $100,000.

(b) Twenty-four Hour Notification. Each licensee or registrant shall within 24 hours notify the Agency by 1) telephone and 2) telegram, mailgram or facsimile of any incident involving any source of radiation possessed by him and which may have caused or threatens to cause:

(1) A dose to the whole body of any individual 5 rems or more of radiation; a dose to the skin of the whole body of any individual of 30 rems or more of radiation; or a dose to the feet, ankles, hands, or forearms of 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 A, Table II, or

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

(4) Damage to property in excess of $1,000.

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

A.5.4 Reports of Overexposures and Excessive Levels and Concentrations.

(a) In addition to any notification required by 5.3, each licensee shall make a report in writing within 30 days to the Agency of:

(1) each exposure of an individual to radiation in excess of the applicable limits in A.2.1 or A.2.4 (a) or the license;

(2) each exposure of an individual to radioactive material in excess of the applicable limits in A.2.3 (a) (1), A.2.3 (a) (2), A.2.4 (b) or the license;

A.5.4 (a) (3)

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

(4) any incident for which notification is required by A.5.3; and

(5) 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. Each report required under this paragraph shall describe the extent of exposure of individuals to radiation or to radioactive material, including estimates of each individual's exposure as required by A.5.4 (b); levels of radiation and concentrations of radioactive material involved; the cause of the exposure, levels of concentrations; and corrective steps taken or planned to assure against a recurrence.

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

A.5.5 Vacating Premises. Each specific licensee shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the Agency in writing of intent to vacate. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.

A.5.6 Notifications and Reports to Individuals.

(a) Requirements for notifications and reports to individuals of exposure to radiation or radioactive material are specified in A.6.4 of this part.

(b) When a licensee or registrant is required pursuant to section A.5.4 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of section A.6.4 of this part.

A.5.7 Reports of Personnel Exposure on Termination of Employment or Work. When an individual terminates employment with a licensee or registrant subject to A.3.2, or an individual assigned to work in such a licensee's facility, but not employed by the licensee or registrant, completes his work assignment in the licensee's or registrant's facility, the licensee or registrant shall furnish to the Agency a report of the individual's exposure to radiation and radioactive material, incurred during the period of employment or work assignment in the licensee's or registrant's facility, containing information recorded by the licensee pursuant to A.5.1 (a) and A.2.7, or the registrant pursuant to A.5.1 (a). Such report shall be furnished within 30 days after the exposure of the individual has been determined by the licensee or registrant, or 90 days after the date of termination of employment or work assignment, whichever is earlier.

A.6 NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

A.6.1 Purpose and Scope. This subpart establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in work under a license or registration and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, licenses and certificates of registration issued thereunder regarding radiological working conditions. The regulations in this subpart apply to all persons who receive, possess, use, own or transfer radiation sources licensed by or registered with the Agency pursuant to these regulations.

A.6.2 Posting of Notices to Workers.

(a) Each licensee or registrant shall post current copies of the following documents:

(1) The regulations in this part;

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

(3) The operating procedures applicable to work under the license or registration;

(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to the Act, and any response from the licensee or registrant.

(b) If posting of a document specified in A.6.2 (a) (1), (2), or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Agency Form RCA-1 "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a controlled area.

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

(e) Agency documents posted pursuant to A.6.2 (a) (4) shall be posted within 2 working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within 2 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

A.6.3 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 sources of radiation in such portions of the restricted area; shall be instructed in the health protection problems associated with exposure to radiation or radioactive material, 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 these regulations, licenses, and certificates of registration for the protection of personnel from exposures to radiation or radioactive material occurring in such areas; shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of the Act, these regulations, licenses, and certificates of registration or unnecessary exposure to radiation or 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 shall be furnished pursuant to A.6.4 (b); and shall be instructed in the potential hazards of prenatal exposure to radiation. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

A.6.4 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 Agency regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to Agency regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and 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 Rhode Island Rules and Regulations for the Control of Radiation, subpart A.6. You should preserve this report for further reference."

(b) Each licensee or registrant shall advise each worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to A.5.1 (a) and (c).

A.6.4 (c)

(c) Each licensee or registrant shall furnish to each worker a report of the worker's exposure to radiation or radioactive material on termination of employment. Such report shall be furnished within 30 days from the time of termination, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; shall cover, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or x-ray equipment registered with the Agency; and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(d) When a licensee or registrant is required pursuant to A.5.4 and A.5.7 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

A.6.5 Presence of Representatives of Licenses or Registrants and Workers During Inspection.

(a) Each licensee or registrant shall afford to the Agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.

(b) During an inspection, Agency inspectors may consult privately with workers as specified in A.6.6. The licensee or registrant may accompany Agency 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 Agency inspections, the licensee or registrant 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 work under control of the licensee or registrant and shall have received instructions as specified in A.6.3.

(e) Different representatives of licensees or registrants 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 or registrant and the workers' representative an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

A.6.5 (g)

(g) Notwithstanding the other provisions of this section, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

A.6.6 Consultation with Workers During Inspections.

(a) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Agency regulations, licenses and certificates of registration 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, these regulations, license or certificate of registration condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered x-ray system under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of A.6.7 (a).

(c) The provisions of A.6.6 (b) shall not be interpreted as authorization to disregard instructions pursuant A.6.3.

A.6.7 Requests by Workers for Inspections.

(a) Any worker or representative of workers who believes that a violation of the Act, these regulations or license or certificate of registration conditions exists or has occurred in work under a license or registration 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 Agency. 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 the workers. A copy shall be provided to the licensee or registrant by the Agency 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 Agency, except for good cause shown.

(b) If, upon receipt of such notice, the Agency Administrator determines that the complaint meets the requirements set forth in A.6.7 (a), 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 pursuant to this section need not be limited to matters referred to in the complaint.

A.6.7 (c)

(c) No licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this part.

A.6.8 Inspections Not Warranted; Informal Review.

(a) If the Agency determines, with respect to a complaint under A.6.7, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Agency 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 Director of Health who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Director of Health who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Director of Health may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the Director of Health shall affirm, modify, or reverse the determination of the Agency and furnish the complainant and the licensee or registrant a written notification of his decision and the reason therefor.

(b) If the Agency determines that an inspection is not warranted because the requirements of A.6.7 (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 A.6.7 (a).

A.7 COMPLIANCE PROCEDURES

To ensure compliance with these regulations, the Agency shall proceed in accordance with the provisions of this subpart, as appropriate.

A.7.1 Notice of Violation.

(a) If, upon inspection or investigation, the administrator or his authorized representative finds that a registrant or licensee has violated any of the provisions of the Act, these regulations, or any rules, orders or conditions imposed pursuant to the Act, he may issue a written Notice of Violation to the registrant or licensee.

(b) Each Notice of Violation shall describe the nature of the violation(s), including a reference to the provision(s) of the law, regulation, rule, order or condition alleged to have been violated.

A.7.1 (c)

(c) Each Notice of Violation shall require a consent agreement, whereby the registrant or licensee shall provide a written response to the Agency within ten days of the service of the Notice of Violation. The response shall specify the corrective actions which the registrant or licensee proposes to take, along with an es mate of the time required to implement such actions. If the response is acceptable to the Agency, and the consent agreement is implemente , no further action will be taken.

A.7.2 Order of Abatement. If, upon inspection or investigation, the administrator or his authorized representative finds that a registrant or licensee has violated any of the provisions of the Act, these regulations, or any rules, orders or conditions imposed pursuant to the Act, or a consent agreement, he may issue an Order of Abatement. Also, if a registrant or licensee fails to respond within ten days to a Notice of Violation, the Agency may issue an Order of Abatement.

(a) Each Order of Abatement shall describe the nature of the violation(s), including a reference to the provision(s) of the law, regulation, rule, order, condition, or consent agreement alleged to have been violated.

(b) Each Order of Abatement shall fix a reasonable time for the abatement of violations, which time shall not be later than ten days from the date of service of the order.

(c) Each Order of Abatement issued under this section shall be prominently posted so as to be conspicuously visible to employees and patrons of the licensee or registrant.

A.7.3 Emergency Authority.

(a) Whenever the administrator finds that an emergency exists requiring immediate action to protect the public health or welfare, he may issue an order stating that an emergency exists and requiring that such action be taken as he deems necessary to meet the emergency. Such order shall be effective immediately.

(b) Any person to whom an emergency order is directed shall comply therewith immediately.

A.7.4 Orders of Suspension, Modification, and Revocation.

(a) An order may be issued for mmediate suspension of a registration or license, or a portion thereof, as necessary to remove an immediate threat to the health or safety of a registrant's or licensee's employees or the public. Non-payment of fees beyond the due date may also result in the suspension of a registration or license.

(b) An order for the modification of a registration or license, in whole or in part, may be issued as an enforcement sanction, when it is determined that a registrant's or licensee's operations or activities must be limited or modified to protect the health, safety or interest of the registrant's or licensee's employees or the public.

(c) An order may be issued to revoke a registration or license when

A.7.4 (c) (1)

(1) The registrant's or licensee's performance shows that he is not qualified to perform the activities covered by the registration or license; or

(2) The registrant or licensee refuses to correct violations; or

(3) A registrant or licensee does not comply with an Order of Abatement, or

(4) A registrant's or licensee's response to a notice of violation indicates inability or unwillingness to maintain compliance with regulatory requirements; or

(5) Any material false statement is made in the application or in any statement of fact required under these regulations.

A.7.5 Agency Hearings. In any proceeding under these regulations for granting, suspending, revoking, or modifying any registration or license, or for determining compliance with or granting exemptions from rules and regulations of the Agency, the Agency or any person whose interest may be affected by the proceeding may request and shall be afforded an opportunity for a hearing on the record.

A.7.6 Formal Hearings.

(a) Any person aggrieved by a finding or order of the Agency may request a hearing before the Director of Health or his authorized representative, at any time within fifteen days after notification. The Director of Health may affirm the finding or order of the Agency or reverse or modify it.

(b) Any person to whom an emergency order is directed shall, on application to the Director of Health, be afforded a hearing within fifteen days. On the basis of such hearing, the Director of Health shall continue such order in effect, revoke it, or modify it.

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
Actinium (89)	Ac 227	S	$2X10^{-12}$	$6X10^{-5}$	$8X10^{-14}$	$2X10^{-6}$
		I	$3X10^{-11}$	$9X10^{-3}$	$9X10^{-13}$	$3X10^{-4}$
	Ac 228	S	$8X10^{-8}$	$3X10^{-3}$	$3X10^{-9}$	$9X10^{-5}$
		I	$2X10^{-8}$	$3X10^{-3}$	$6X10^{-10}$	$9X10^{-5}$
Americium (95)	Am 241	S	$6X10^{-12}$	$1X10^{-4}$	$2X10^{-13}$	$4X10^{-6}$
		I	$1X10^{-10}$	$8X10^{-4}$	$4X10^{-12}$	$2X10^{-5}$
	Am 242 m	S	$6X10^{-12}$	$1X10^{-4}$	$2X10^{-13}$	$4X10^{-6}$
		I	$3X10^{-10}$	$3X10^{-3}$	$9X10^{-12}$	$9X10^{-5}$
	Am 242	S	$4X10^{-8}$	$4X10^{-3}$	$1X10^{-9}$	$1X10^{-4}$
		I	$5X10^{-8}$	$4X10^{-3}$	$2X10^{-9}$	$1X10^{-4}$
	Am 243	S	$6X10^{-12}$	$1X10^{-4}$	$2X10^{-13}$	$4X10^{-6}$
		I	$1X10^{-10}$	$8X10^{-4}$	$4X10^{-12}$	$3X10^{-5}$
	Am 244	S	$4X10^{-6}$	$1X10^{-1}$	$1X10^{-7}$	$5X10^{-3}$
		I	$2X10^{-5}$	$1X10^{-1}$	$8X10^{-7}$	$5X10^{-3}$
Antimony (51)	Sb 122	S	$2X10^{-7}$	$8X10^{-4}$	$6X10^{-9}$	$3X10^{-5}$
		I	$1X10^{-7}$	$8X10^{-4}$	$5X10^{-9}$	$3X10^{-5}$
	Sb 124	S	$2X10^{-7}$	$7X10^{-4}$	$5X10^{-9}$	$2X10^{-5}$
		I	$2X10^{-8}$	$7X10^{-4}$	$7X10^{-10}$	$2X10^{-5}$
	Sb 125	S	$5X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$3X10^{-8}$	$3X10^{-3}$	$9X10^{-10}$	$1X10^{-4}$
Argon (18)	A 37	Sub[2]	$6X10^{-3}$	------	$1X10^{-4}$	------
	A 41	Sub	$2X10^{-6}$	------	$4X10^{-8}$	------
Arsenic (33)	As 73	S	$2X10^{-6}$	$1X10^{-2}$	$7X10^{-8}$	$5X10^{-4}$
		I	$4X10^{-7}$	$1X10^{-2}$	$1X10^{-8}$	$5X10^{-4}$
	As 74	S	$3X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$5X10^{-5}$
		I	$1X10^{-7}$	$2X10^{-3}$	$4X10^{-9}$	$5X10^{-5}$
	As 76	S	$1X10^{-7}$	$6X10^{-4}$	$4X10^{-9}$	$2X10^{-5}$
		I	$1X10^{-7}$	$6X10^{-4}$	$3X10^{-9}$	$2X10^{-5}$
	As 77	S	$5X10^{-7}$	$2X10^{-3}$	$2X10^{-8}$	$8X10^{-5}$
		I	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$8X10^{-5}$
Astatine (85)	At 211	S	$7X10^{-9}$	$5X10^{-5}$	$2X10^{-10}$	$2X10^{-6}$
		I	$3X10^{-8}$	$2X10^{-3}$	$1X10^{-9}$	$7X10^{-5}$
Barium (56)	Ba 131	S	$1X10^{-6}$	$5X10^{-3}$	$4X10^{-8}$	$2X10^{-4}$
		I	$4X10^{-7}$	$5X10^{-3}$	$1X10^{-8}$	$2X10^{-4}$
	Ba 140	S	$1X10^{-7}$	$8X10^{-4}$	$4X10^{-9}$	$3X10^{-5}$
		I	$4X10^{-8}$	$7X10^{-4}$	$1X10^{-9}$	$2X10^{-5}$
Berkelium (97)	Bk 249	S	$9X10^{-10}$	$2X10^{-2}$	$3X10^{-11}$	$6X10^{-4}$
		I	$1X10^{-7}$	$2X10^{-2}$	$4X10^{-9}$	$6X10^{-4}$
	Bk 250	S	$1X10^{-7}$	$6X10^{-3}$	$5X10^{-9}$	$2X10^{-4}$
		I	$1X10^{-6}$	$6X10^{-3}$	$4X10^{-8}$	$2X10^{-4}$
Beryllium (4)	Be 7	S	$6X10^{-6}$	$5X10^{-2}$	$2X10^{-7}$	$2X10^{-3}$
		I	$1X10^{-6}$	$5X10^{-2}$	$4X10^{-8}$	$2X10^{-3}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
Bismuth (83)	Bi 206	S	$2X10^{-7}$	$1X10^{-3}$	$6X10^{-9}$	$4X10^{-5}$
		I	$1X10^{-7}$	$1X10^{-3}$	$5X10^{-9}$	$4X10^{-5}$
	Bi 207	S	$2X10^{-7}$	$2X10^{-3}$	$6X10^{-9}$	$6X10^{-5}$
		I	$1X10^{-8}$	$2X10^{-3}$	$5X10^{-10}$	$6X10^{-5}$
	Bi 210	S	$6X10^{-9}$	$1X10^{-3}$	$2X10^{-10}$	$4X10^{-5}$
		I	$6X10^{-9}$	$1X10^{-3}$	$2X10^{-10}$	$4X10^{-5}$
	Bi 212	S	$1X10^{-7}$	$1X10^{-2}$	$3X10^{-9}$	$4X10^{-4}$
		I	$2X10^{-7}$	$1X10^{-2}$	$7X10^{-9}$	$4X10^{-4}$
Bromine (35)	Br 82	S	$1X10^{-6}$	$8X10^{-3}$	$4X10^{-8}$	$3X10^{-4}$
		I	$2X10^{-7}$	$1X10^{-3}$	$6X10^{-9}$	$4X10^{-5}$
Cadmium (48)	Cd 109	S	$5X10^{-8}$	$5X10^{-3}$	$2X10^{-9}$	$2X10^{-4}$
		I	$7X10^{-8}$	$5X10^{-3}$	$3X10^{-9}$	$2X10^{-4}$
	Cd 115 m	S	$4X10^{-8}$	$7X10^{-4}$	$1X10^{-9}$	$3X10^{-5}$
		I	$4X10^{-8}$	$7X10^{-4}$	$1X10^{-9}$	$3X10^{-5}$
	Cd 115	S	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$3X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$6X10^{-9}$	$4X10^{-5}$
Calcium (20)	Ca 45	S	$3X10^{-8}$	$3X10^{-4}$	$1X10^{-9}$	$9X10^{-6}$
		I	$1X10^{-7}$	$5X10^{-3}$	$4X10^{-9}$	$2X10^{-4}$
	Ca 47	S	$2X10^{-7}$	$1X10^{-3}$	$6X10^{-9}$	$5X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$6X10^{-9}$	$3X10^{-5}$
Californium (98)	Cf 249	S	$2X10^{-12}$	$1X10^{-4}$	$5X10^{-14}$	$4X10^{-6}$
		I	$1X10^{-10}$	$7X10^{-4}$	$3X10^{-12}$	$2X10^{-5}$
	Cf 250	S	$5X10^{-12}$	$4X10^{-4}$	$2X10^{-13}$	$1X10^{-5}$
		I	$1X10^{-10}$	$7X10^{-4}$	$3X10^{-12}$	$3X10^{-5}$
	Cf 251	S	$2X10^{-12}$	$1X10^{-4}$	$6X10^{-14}$	$4X10^{-6}$
		I	$1X10^{-10}$	$8X10^{-4}$	$3X10^{-12}$	$3X10^{-5}$
	Cf 252	S	$2X10^{-11}$	$7X10^{-4}$	$7X10^{-13}$	$2X10^{-5}$
		I	$1X10^{-10}$	$7X10^{-4}$	$4X10^{-12}$	$2X10^{-5}$
	Cf 253	S	$8X10^{-10}$	$4X10^{-3}$	$3X10^{-11}$	$1X10^{-4}$
		I	$8X10^{-10}$	$4X10^{-3}$	$3X10^{-11}$	$1X10^{-4}$
	Cf 254	S	$5X10^{-12}$	$4X10^{-6}$	$2X10^{-13}$	$1X10^{-7}$
		I	$5X10^{-12}$	$4X10^{-6}$	$2X10^{-13}$	$1X10^{-7}$
Carbon (6)	C 14	S	$4X10^{-6}$	$2X10^{-2}$	$1X10^{-7}$	$8X10^{-4}$
	(CO_2)	Sub	$5X10^{-5}$	------	$1X10^{-6}$	-------
Cerium (58)	Ce 141	S	$4X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$9X10^{-5}$
		I	$2X10^{-7}$	$3X10^{-3}$	$5X10^{-9}$	$9X10^{-5}$
	Ce 143	S	$3X10^{-7}$	$1X10^{-3}$	$9X10^{-9}$	$4X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$7X10^{-9}$	$4X10^{-5}$
	Ce 144	S	$1X10^{-8}$	$5X10^{-4}$	$3X10^{-10}$	$1X10^{-5}$
		I	$6X10^{-9}$	$3X10^{-4}$	$2X10^{-10}$	$1X10^{-5}$
Cesium (55)	Cs 131	S	$1X10^{-5}$	$7X10^{-2}$	$4X10^{-7}$	$2X10^{-3}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
		I	$3X10^{-6}$	$3X10^{-2}$	$1X10^{-7}$	$9X10^{-4}$
	Cs 134 m	S	$4X10^{-5}$	$2X10^{-1}$	$1X10^{-6}$	$6X10^{-3}$
		I	$6X10^{-6}$	$3X10^{-2}$	$2X10^{-7}$	$1X10^{-3}$
	Cs 134	S	$4X10^{-8}$	$3X10^{-4}$	$1X10^{-9}$	$9X10^{-6}$
		I	$1X10^{-8}$	$1X10^{-3}$	$4X10^{-10}$	$4X10^{-5}$
	Cs 135	S	$5X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$9X10^{-8}$	$7X10^{-3}$	$3X10^{-9}$	$2X10^{-4}$
	Cs 136	S	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$9X10^{-5}$
		I	$2X10^{-7}$	$2X10^{-3}$	$6X10^{-9}$	$6X10^{-5}$
	Cs 137	S	$6X10^{-8}$	$4X10^{-4}$	$2X10^{-9}$	$2X10^{-5}$
		I	$1X10^{-8}$	$1X10^{-3}$	$5X10^{-10}$	$4X10^{-5}$
Chlorine (17)	Cl 36	S	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$8X10^{-5}$
		I	$2X10^{-6}$	$2X10^{-3}$	$8X10^{-10}$	$6X10^{-5}$
	Cl 38	S	$3X10^{-6}$	$1X10^{-2}$	$9X10^{-8}$	$4X10^{-4}$
		I	$2X10^{-6}$	$1X10^{-2}$	$7X10^{-8}$	$4X10^{-4}$
Chromium (24)	Cr 51	S	$1X10^{-5}$	$5X10^{-2}$	$4X10^{-7}$	$2X10^{-3}$
		I	$2X10^{-6}$	$5X10^{-2}$	$8X10^{-8}$	$2X10^{-3}$
Cobalt (27)	Co 57	S	$3X10^{-6}$	$2X10^{-2}$	$1X10^{-7}$	$5X10^{-4}$
		I	$2X10^{-7}$	$1X10^{-2}$	$6X10^{-9}$	$4X10^{-4}$
	Co 58 m	S	$2X10^{-5}$	$8X10^{-2}$	$6X10^{-7}$	$3X10^{-3}$
		I	$9X10^{-6}$	$6X10^{-2}$	$3X10^{-7}$	$2X10^{-3}$
	Co 58	S	$8X10^{-7}$	$4X10^{-3}$	$3X10^{-8}$	$1X10^{-4}$
		I	$5X10^{-8}$	$3X10^{-3}$	$2X10^{-9}$	$9X10^{-5}$
	Co 60	S	$3X10^{-7}$	$1X10^{-3}$	$1X10^{-8}$	$5X10^{-5}$
		I	$9X10^{-9}$	$1X10^{-3}$	$3X10^{-10}$	$3X10^{-5}$
Copper (29)	Cu 64	S	$2X10^{-6}$	$1X10^{-2}$	$7X10^{-8}$	$3X10^{-4}$
		I	$1X10^{-6}$	$6X10^{-3}$	$4X10^{-8}$	$2X10^{-4}$
Curium (96)	Cm 242	S	$1X10^{-10}$	$7X10^{-4}$	$4X10^{-12}$	$2X10^{-5}$
		I	$2X10^{-10}$	$7X10^{-4}$	$6X10^{-12}$	$3X10^{-5}$
	Cm 243	S	$6X10^{-12}$	$1X10^{-4}$	$2X10^{-13}$	$5X10^{-6}$
		I	$1X10^{-10}$	$7X10^{-4}$	$3X10^{-12}$	$2X10^{-5}$
	Cm 244	S	$9X10^{-12}$	$2X10^{-4}$	$3X10^{-13}$	$7X10^{-6}$
		I	$1X10^{-10}$	$8X10^{-4}$	$3X10^{-12}$	$3X10^{-5}$
	Cm 245	S	$5X10^{-12}$	$1X10^{-4}$	$2X10^{-13}$	$4X10^{-6}$
		I	$1X10^{-10}$	$8X10^{-4}$	$4X10^{-12}$	$3X10^{-5}$
	Cm 246	S	$5X10^{-12}$	$1X10^{-4}$	$2X10^{-13}$	$4X10^{-6}$
		I	$1X10^{-10}$	$8X10^{-4}$	$4X10^{-12}$	$3X10^{-5}$
	Cm 247	S	$5X10^{-12}$	$1X10^{-4}$	$2X10^{-13}$	$4X10^{-6}$
		I	$1X10^{-10}$	$6X10^{-4}$	$4X10^{-12}$	$2X10^{-5}$
	Cm 248	S	$6X10^{-13}$	$1X10^{-5}$	$2X10^{-14}$	$4X10^{-7}$
		I	$1X10^{-11}$	$4X10^{-5}$	$4X10^{-13}$	$1X10^{-6}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
	Cm 249	S	$1X10^{-5}$	$6X10^{-2}$	$4X10^{-7}$	$2X10^{-3}$
		I	$1X10^{-5}$	$6X10^{-2}$	$4X10^{-7}$	$2X10^{-3}$
Dysprosium (66)	Dy 165	S	$3X10^{-6}$	$1X10^{-2}$	$9X10^{-8}$	$4X10^{-4}$
		I	$2X10^{-6}$	$1X10^{-2}$	$7X10^{-8}$	$4X10^{-4}$
	Dy 166	S	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$4X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$7X10^{-9}$	$4X10^{-5}$
Einsteinium (99)	Es 253	S	$8X10^{-10}$	$7X10^{-4}$	$3X10^{-11}$	$2X10^{-5}$
		I	$6X10^{-10}$	$7X10^{-4}$	$2X10^{-11}$	$2X10^{-5}$
	Es 254 m	S	$5X10^{-9}$	$5X10^{-4}$	$2X10^{-10}$	$2X10^{-5}$
		I	$6X10^{-9}$	$5X10^{-4}$	$2X10^{-10}$	$2X10^{-5}$
	Es 254	S	$2X10^{-11}$	$4X10^{-4}$	$6X10^{-13}$	$1X10^{-5}$
		I	$1X10^{-10}$	$4X10^{-4}$	$4X10^{-12}$	$1X10^{-5}$
	Es 255	S	$5X10^{-10}$	$8X10^{-4}$	$2X10^{-11}$	$3X10^{-5}$
		I	$4X10^{-10}$	$8X10^{-4}$	$1X10^{-11}$	$3X10^{-5}$
Erbium (68)	Er 169	S	$6X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$9X10^{-5}$
		I	$4X10^{-7}$	$3X10^{-3}$	$1X10^{-8}$	$9X10^{-5}$
	Er 171	S	$7X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$6X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
Europium (63)	Eu 152	S	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$6X10^{-5}$
	(T/2=9.2 hrs)	I	$3X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$6X10^{-5}$
	Eu 152	S	$1X10^{-8}$	$2X10^{-3}$	$4X10^{-10}$	$8X10^{-5}$
	(T/2=13 yrs)	I	$2X10^{-8}$	$2X10^{-3}$	$6X10^{-10}$	$8X10^{-5}$
	Eu 154	S	$4X10^{-9}$	$6X10^{-4}$	$1X10^{-10}$	$2X10^{-5}$
		I	$7X10^{-9}$	$6X10^{-4}$	$2X10^{-10}$	$2X10^{-5}$
	Eu 155	S	$9X10^{-8}$	$6X10^{-3}$	$3X10^{-9}$	$2X10^{-4}$
		I	$7X10^{-8}$	$6X10^{-3}$	$3X10^{-9}$	$2X10^{-4}$
Fermium (100)	Fm 254	S	$6X10^{-8}$	$4X10^{-3}$	$2X10^{-9}$	$1X10^{-4}$
		I	$7X10^{-8}$	$4X10^{-3}$	$2X10^{-9}$	$1X10^{-4}$
	Fm 255	S	$2X10^{-8}$	$1X10^{-3}$	$6X10^{-10}$	$3X10^{-5}$
		I	$1X10^{-8}$	$1X10^{-3}$	$4X10^{-10}$	$3X10^{-5}$
	Fm 256	S	$3X10^{-9}$	$3X10^{-5}$	$1X10^{-10}$	$9X10^{-7}$
		I	$2X10^{-9}$	$3X10^{-5}$	$6X10^{-11}$	$9X10^{-7}$
Fluorine (9)	F 18	S	$5X10^{-6}$	$2X10^{-2}$	$2X10^{-7}$	$8X10^{-4}$
		I	$3X10^{-6}$	$1X10^{-2}$	$9X10^{-8}$	$5X10^{-4}$
Gadolinium (64)	Gd 153	S	$2X10^{-7}$	$6X10^{-3}$	$8X10^{-9}$	$2X10^{-4}$
		I	$9X10^{-8}$	$6X10^{-3}$	$3X10^{-9}$	$2X10^{-4}$
	Gd 159	S	$5X10^{-7}$	$2X10^{-3}$	$2X10^{-8}$	$8X10^{-5}$
		I	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$8X10^{-5}$
Gallium (31)	Ga 72	S	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$4X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$6X10^{-9}$	$4X10^{-5}$
Germanium (32)	Ge 71	S	$1X10^{-5}$	$5X10^{-2}$	$4X10^{-7}$	$2X10^{-3}$
		I	$6X10^{-6}$	$5X10^{-2}$	$2X10^{-7}$	$2X10^{-3}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
Gold (79)	Au 196	S	$1X10^{-6}$	$5X10^{-3}$	$4X10^{-8}$	$2X10^{-4}$
		I	$6X10^{-7}$	$4X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
	Au 198	S	$3X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$5X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$5X10^{-5}$
	Au 199	S	$1X10^{-6}$	$5X10^{-3}$	$4X10^{-8}$	$2X10^{-4}$
		I	$8X10^{-7}$	$4X10^{-3}$	$3X10^{-8}$	$2X10^{-4}$
Hafnium (72)	Hf 181	S	$4X10^{-8}$	$2X10^{-3}$	$1X10^{-9}$	$7X10^{-5}$
		I	$7X10^{-8}$	$2X10^{-3}$	$3X10^{-9}$	$7X10^{-5}$
Holmium (67)	Ho 166	S	$2X10^{-7}$	$9X10^{-4}$	$7X10^{-9}$	$3X10^{-5}$
		I	$2X10^{-7}$	$9X10^{-4}$	$6X10^{-9}$	$3X10^{-5}$
Hydrogen (1)	H 3	S	$5X10^{-6}$	$1X10^{-1}$	$2X10^{-7}$	$3X10^{-3}$
		I	$5X10^{-6}$	$1X10^{-1}$	$2X10^{-7}$	$3X10^{-3}$
		Sub	$2X10^{-3}$	-----	$4X10^{-5}$	-----
Indium (49)	In 113 m	S	$8X10^{-6}$	$4X10^{-2}$	$3X10^{-7}$	$1X10^{-3}$
		I	$7X10^{-6}$	$4X10^{-2}$	$2X10^{-7}$	$1X10^{-3}$
	In 114 m	S	$1X10^{-7}$	$5X10^{-4}$	$4X10^{-9}$	$2X10^{-5}$
		I	$2X10^{-8}$	$5X10^{-4}$	$7X10^{-10}$	$2X10^{-5}$
	In 115 m	S	$2X10^{-6}$	$1X10^{-2}$	$8X10^{-8}$	$4X10^{-4}$
		I	$2X10^{-6}$	$1X10^{-2}$	$6X10^{-8}$	$4X10^{-4}$
	In 115	S	$2X10^{-7}$	$3X10^{-3}$	$9X10^{-9}$	$9X10^{-5}$
		I	$3X10^{-8}$	$3X10^{-3}$	$1X10^{-9}$	$9X10^{-5}$
Iodine (53)	I 125	S	$5X10^{-9}$	$4X10^{-5}$	$8X10^{-11}$	$2X10^{-7}$
		I	$2X10^{-7}$	$6X10^{-3}$	$6X10^{-9}$	$2X10^{-4}$
	I 126	S	$8X10^{-9}$	$5X10^{-5}$	$9X10^{-11}$	$3X10^{-7}$
		I	$3X10^{-7}$	$3X10^{-3}$	$1X10^{-8}$	$9X10^{-5}$
	I 129	S	$2X10^{-9}$	$1X10^{-5}$	$2X10^{-11}$	$6X10^{-8}$
		I	$7X10^{-8}$	$6X10^{-3}$	$2X10^{-9}$	$2X10^{-4}$
	I 131	S	$9X10^{-9}$	$6X10^{-5}$	$2X10^{-10}$	$2X10^{-7}$
		I	$3X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$3X10^{-5}$
	I 132	S	$2X10^{-7}$	$2X10^{-3}$	$1X10^{-9}$	$6X10^{-6}$
		I	$9X10^{-7}$	$5X10^{-3}$	$3X10^{-8}$	$8X10^{-4}$
	I 133	S	$3X10^{-8}$	$2X10^{-4}$	$4X10^{-10}$	$2X10^{-6}$
		I	$2X10^{-7}$	$1X10^{-3}$	$7X10^{-9}$	$4X10^{-5}$
	I 134	S	$5X10^{-7}$	$4X10^{-3}$	$6X10^{-9}$	$2X10^{-5}$
		I	$3X10^{-6}$	$2X10^{-2}$	$1X10^{-7}$	$6X10^{-4}$
	I 135	S	$1X10^{-7}$	$7X10^{-4}$	$1X10^{-9}$	$4X10^{-6}$
		I	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$7X10^{-5}$
Iridium (77)	Ir 190	S	$1X10^{-6}$	$6X10^{-3}$	$4X10^{-8}$	$2X10^{-4}$
		I	$4X10^{-7}$	$5X10^{-3}$	$1X10^{-9}$	$2X10^{-5}$
	Ir 192	S	$1X10^{-7}$	$1X10^{-3}$	$4X10^{-10}$	$4X10^{-5}$
		I	$3X10^{-8}$	$1X10^{-3}$	$9X10^{-10}$	$4X10^{-5}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
	Ir 194	S	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$3X10^{-5}$
		I	$2X10^{-7}$	$9X10^{-4}$	$5X10^{-9}$	$3X10^{-5}$
Iron (26)	Fe 55	S	$9X10^{-7}$	$2X10^{-2}$	$3X10^{-8}$	$8X10^{-4}$
		I	$1X10^{-6}$	$7X10^{-2}$	$3X10^{-8}$	$2X10^{-3}$
	Fe 59	S	$1X10^{-7}$	$2X10^{-3}$	$5X10^{-9}$	$6X10^{-5}$
		I	$5X10^{-8}$	$2X10^{-3}$	$2X10^{-9}$	$5X10^{-5}$
Krypton (36)	Kr 85 m	Sub	$6X10^{-6}$	------	$1X10^{-7}$	------
	Kr 85	Sub	$1X10^{-5}$	------	$3X10^{-7}$	------
	Kr 87	Sub	$1X10^{-6}$	------	$2X10^{-8}$	------
	Kr 88	Sub	$1X10^{-6}$	------	$2X10^{-8}$	------
Lanthanum (57)	La 140	S	$2X10^{-7}$	$7X10^{-4}$	$5X10^{-9}$	$2X10^{-5}$
		I	$1X10^{-7}$	$7X10^{-4}$	$4X10^{-9}$	$2X10^{-5}$
Lead (82)	Pb 203	S	$3X10^{-6}$	$1X10^{-2}$	$9X10^{-8}$	$4X10^{-4}$
		I	$2X10^{-6}$	$1X10^{-2}$	$6X10^{-8}$	$4X10^{-4}$
	Pb 210	S	$1X10^{-10}$	$4X10^{-6}$	$4X10^{-12}$	$1X10^{-7}$
		I	$2X10^{-10}$	$5X10^{-3}$	$8X10^{-12}$	$2X10^{-4}$
	Pb 212	S	$2X10^{-8}$	$6X10^{-4}$	$6X10^{-10}$	$2X10^{-5}$
		I	$2X10^{-8}$	$5X10^{-4}$	$7X10^{-10}$	$2X10^{-5}$
Lutetium (71)	Lu 177	S	$6X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$5X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
Manganese (25)	Mn 52	S	$2X10^{-7}$	$1X10^{-3}$	$7X10^{-9}$	$3X10^{-5}$
		I	$1X10^{-7}$	$9X10^{-4}$	$5X10^{-9}$	$3X10^{-5}$
	Mn 54	S	$4X10^{-7}$	$4X10^{-3}$	$1X10^{-9}$	$1X10^{-4}$
		I	$4X10^{-8}$	$3X10^{-3}$	$1X10^{-9}$	$1X10^{-4}$
	Mn 56	S	$8X10^{-7}$	$4X10^{-3}$	$3X10^{-8}$	$1X10^{-4}$
		I	$5X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
Mercury (80)	Hg 197 m	S	$7X10^{-7}$	$6X10^{-3}$	$3X10^{-8}$	$2X10^{-4}$
		I	$8X10^{-7}$	$5X10^{-3}$	$3X10^{-8}$	$2X10^{-4}$
	Hg 197	S	$1X10^{-6}$	$9X10^{-3}$	$4X10^{-8}$	$3X10^{-4}$
		I	$3X10^{-6}$	$1X10^{-2}$	$9X10^{-8}$	$5X10^{-4}$
	Hg 203	S	$7X10^{-8}$	$5X10^{-4}$	$2X10^{-9}$	$2X10^{-5}$
		I	$1X10^{-7}$	$3X10^{-3}$	$4X10^{-9}$	$1X10^{-4}$
Molybdenum (42)	Mo 99	S	$7X10^{-7}$	$5X10^{-3}$	$3X10^{-8}$	$2X10^{-4}$
		I	$2X10^{-7}$	$1X10^{-3}$	$7X10^{-9}$	$4X10^{-5}$
Neodymium (60)	Nd 144	S	$8X10^{-11}$	$2X10^{-3}$	$3X10^{-12}$	$7X10^{-5}$
		I	$3X10^{-10}$	$2X10^{-3}$	$1X10^{-11}$	$8X10^{-5}$
	Nd 147	S	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$6X10^{-5}$
		I	$2X10^{-7}$	$2X10^{-3}$	$8X10^{-9}$	$6X10^{-5}$
	Nd 149	S	$2X10^{-6}$	$8X10^{-3}$	$6X10^{-8}$	$3X10^{-4}$
		I	$1X10^{-6}$	$8X10^{-3}$	$5X10^{-8}$	$3X10^{-4}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
Neptunium (93)	Np 237	S	$4X10^{-12}$	$9X10^{-5}$	$1X10^{-13}$	$3X10^{-6}$
		I	$1X10^{-10}$	$9X10^{-4}$	$4X10^{-12}$	$3X10^{-5}$
	Np 239	S	$8X10^{-7}$	$4X10^{-3}$	$3X10^{-8}$	$1X10^{-4}$
		I	$7X10^{-7}$	$4X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
Nickel (28)	Ni 59	S	$5X10^{-7}$	$6X10^{-3}$	$2X10^{-8}$	$2X10^{-4}$
		I	$8X10^{-7}$	$6X10^{-2}$	$3X10^{-8}$	$2X10^{-3}$
	Ni 63	S	$6X10^{-8}$	$8X10^{-4}$	$2X10^{-9}$	$3X10^{-5}$
		I	$3X10^{-7}$	$2X10^{-2}$	$1X10^{-8}$	$7X10^{-4}$
	Ni 65	S	$9X10^{-7}$	$4X10^{-3}$	$3X10^{-8}$	$1X10^{-4}$
		I	$5X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
Niobium (Columbium) (41)	Nb 93 m	S	$1X10^{-7}$	$1X10^{-2}$	$4X10^{-9}$	$4X10^{-4}$
		I	$2X10^{-7}$	$1X10^{-2}$	$5X10^{-9}$	$4X10^{-4}$
	Nb 95	S	$5X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$1X10^{-7}$	$3X10^{-3}$	$3X10^{-9}$	$1X10^{-4}$
	Nb 97	S	$6X10^{-6}$	$3X10^{-2}$	$2X10^{-7}$	$9X10^{-4}$
		I	$5X10^{-6}$	$3X10^{-2}$	$2X10^{-7}$	$9X10^{-4}$
Osmium (76)	Os 185	S	$5X10^{-7}$	$2X10^{-3}$	$2X10^{-8}$	$7X10^{-5}$
		I	$5X10^{-8}$	$2X10^{-3}$	$2X10^{-9}$	$7X10^{-5}$
	Os 191 m	S	$2X10^{-5}$	$7X10^{-2}$	$6X10^{-7}$	$3X10^{-3}$
		I	$9X10^{-6}$	$7X10^{-2}$	$3X10^{-7}$	$2X10^{-3}$
	Os 191	S	$1X10^{-6}$	$5X10^{-3}$	$4X10^{-8}$	$2X10^{-4}$
		I	$4X10^{-7}$	$5X10^{-3}$	$1X10^{-8}$	$2X10^{-4}$
	Os 193	S	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$6X10^{-5}$
		I	$3X10^{-7}$	$2X10^{-3}$	$9X10^{-9}$	$5X10^{-5}$
Palladium (46)	Pd 103	S	$1X10^{-6}$	$1X10^{-2}$	$5X10^{-8}$	$3X10^{-4}$
		I	$7X10^{-7}$	$8X10^{-3}$	$3X10^{-8}$	$3X10^{-4}$
	Pd 109	S	$6X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$9X10^{-5}$
		I	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$7X10^{-5}$
Phosphorus (15)	P 32	S	$7X10^{-8}$	$5X10^{-4}$	$2X10^{-9}$	$2X10^{-5}$
		I	$8X10^{-8}$	$7X10^{-4}$	$3X10^{-9}$	$2X10^{-5}$
Platinum (78)	Pt 191	S	$8X10^{-7}$	$4X10^{-3}$	$3X10^{-8}$	$1X10^{-4}$
		I	$6X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
	Pt 193m	S	$7X10^{-6}$	$3X10^{-2}$	$2X10^{-7}$	$1X10^{-3}$
		I	$5X10^{-6}$	$3X10^{-2}$	$2X10^{-7}$	$1X10^{-3}$
	Pt 197 m	S	$6X10^{-6}$	$3X10^{-2}$	$2X10^{-7}$	$1X10^{-3}$
		I	$5X10^{-6}$	$3X10^{-2}$	$2X10^{-7}$	$9X10^{-4}$
	Pt 197	S	$8X10^{-7}$	$4X10^{-3}$	$3X10^{-8}$	$1X10^{-4}$
		I	$6X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
Plutonium (94)	Pu 238	S	$2X10^{-12}$	$1X10^{-4}$	$7X10^{-14}$	$5X10^{-6}$
		I	$3X10^{-11}$	$8X10^{-4}$	$1X10^{-12}$	$3X10^{-5}$
	Pu 239	S	$2X10^{-12}$	$1X10^{-4}$	$6X10^{-14}$	$5X10^{-6}$
		I	$4X10^{-11}$	$8X10^{-4}$	$1X10^{-12}$	$3X10^{-5}$
	Pu 240	S	$2X10^{-12}$	$1X10^{-4}$	$6X10^{-14}$	$5X10^{-6}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

[See notes at end of appendix]

Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
		I	$4X10^{-11}$	$8X10^{-4}$	$1X10^{-12}$	$3X10^{-5}$
	Pu 241	S	$9X10^{-11}$	$7X10^{-3}$	$3X10^{-12}$	$2X10^{-4}$
		I	$4X10^{-8}$	$4X10^{-2}$	$1X10^{-9}$	$1X10^{-3}$
	Pu 242	S	$2X10^{-12}$	$1X10^{-4}$	$6X10^{-14}$	$5X10^{-6}$
		I	$4X10^{-11}$	$9X10^{-4}$	$1X10^{-12}$	$3X10^{-5}$
	Pu 243	S	$2X10^{-6}$	$1X10^{-2}$	$6X10^{-8}$	$3X10^{-4}$
		I	$2X10^{-6}$	$1X10^{-2}$	$8X10^{-8}$	$3X10^{-4}$
	Pu 244	S	$2X10^{-12}$	$1X10^{-4}$	$6X10^{-14}$	$4X10^{-6}$
		I	$3X10^{-11}$	$7X10^{-4}$	$1X10^{-12}$	$1X10^{-5}$
Polonium (84)	Po 210	S	$5X10^{-10}$	$2X10^{-5}$	$2X10^{-11}$	$7X10^{-7}$
		I	$2X10^{-10}$	$8X10^{-4}$	$7X10^{-12}$	$3X10^{-5}$
Potassium (19)	K 42	S	$2X10^{-6}$	$9X10^{-3}$	$7X10^{-8}$	$3X10^{-4}$
		I	$1X10^{-7}$	$6X10^{-4}$	$4X10^{-9}$	$2X10^{-5}$
Praseodymium (59)	Pr 142	S	$2X10^{-7}$	$9X10^{-4}$	$7X10^{-9}$	$3X10^{-5}$
		I	$2X10^{-7}$	$9X10^{-4}$	$5X10^{-9}$	$3X10^{-5}$
	Pr 143	S	$3X10^{-7}$	$1X10^{-3}$	$1X10^{-8}$	$5X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$6X10^{-9}$	$5X10^{-5}$
Promethium (61)	Pm 147	S	$6X10^{-8}$	$6X10^{-3}$	$2X10^{-9}$	$2X10^{-4}$
		I	$1X10^{-7}$	$6X10^{-3}$	$3X10^{-9}$	$2X10^{-4}$
	Pm 149	S	$4X10^{-7}$	$1X10^{-3}$	$1X10^{-8}$	$4X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$4X10^{-5}$
Protoactinium (91)	Pa 230	S	$2X10^{-9}$	$7X10^{-3}$	$6X10^{-11}$	$2X10^{-4}$
		I	$8X10^{-10}$	$7X10^{-3}$	$3X10^{-11}$	$2X10^{-4}$
	Pa 231	S	$1X10^{-12}$	$3X10^{-5}$	$4X10^{-14}$	$9X10^{-7}$
		I	$1X10^{-10}$	$8X10^{-4}$	$4X10^{-12}$	$2X10^{-5}$
	Pa 233	S	$6X10^{-7}$	$4X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$2X10^{-7}$	$3X10^{-3}$	$6X10^{-9}$	$1X10^{-4}$
Radium (88)	Ra 223	S	$2X10^{-9}$	$2X10^{-5}$	$6X10^{-11}$	$7X10^{-7}$
		I	$2X10^{-10}$	$2X10^{-4}$	$8X10^{-12}$	$4X10^{-6}$
	Ra 224	S	$5X10^{-9}$	$7X10^{-5}$	$2X10^{-10}$	$2X10^{-6}$
		I	$7X10^{-10}$	$2X10^{-4}$	$2X10^{-11}$	$5X10^{-6}$
	Ra 226	S	$3X10^{-11}$	$4X10^{-7}$	$3X10^{-12}$	$3X10^{-8}$
		I	$5X10^{-11}$	$9X10^{-4}$	$2X10^{-12}$	$3X10^{-5}$
	Ra 228	S	$7X10^{-11}$	$8X10^{-7}$	$2X10^{-12}$	$3X10^{-8}$
		I	$4X10^{-11}$	$7X10^{-4}$	$1X10^{-12}$	$3X10^{-5}$
Radon (86)	Rn 220	S	$3X10^{-7}$	------	$1X10^{-8}$	-------
		I	-------	------	-------	-------
	Rn 222[3]	S	$3X10^{-8}$	------	$3X10^{-9}$	-------
Rhenium (75)	Re 183	S	$3X10^{-6}$	$2X10^{-2}$	$9X10^{-8}$	$6X10^{-4}$
		I	$2X10^{-7}$	$8X10^{-3}$	$5X10^{-9}$	$3X10^{-4}$
	Re 186	S	$6X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$9X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$5X10^{-5}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
	Re 187	S	$9X10^{-6}$	$7X10^{-2}$	$3X10^{-7}$	$3X10^{-3}$
		I	$5X10^{-7}$	$4X10^{-2}$	$2X10^{-8}$	$2X10^{-3}$
	Re 188	S	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$6X10^{-5}$
		I	$2X10^{-7}$	$9X10^{-4}$	$6X10^{-9}$	$3X10^{-5}$
Rhodium (45)	Rh 103 m	S	$8X10^{-5}$	$4X10^{-1}$	$3X10^{-6}$	$1X10^{-2}$
		I	$6X10^{-5}$	$3X10^{-1}$	$2X10^{-6}$	$1X10^{-2}$
	Rh 105	S	$8X10^{-7}$	$4X10^{-3}$	$3X10^{-8}$	$1X10^{-4}$
		I	$5X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
Rubidium (37)	Rb 86	S	$3X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$7X10^{-5}$
		I	$7X10^{-8}$	$7X10^{-4}$	$2X10^{-9}$	$2X10^{-5}$
	Rb 87	S	$5X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$7X10^{-8}$	$5X10^{-3}$	$2X10^{-9}$	$2X10^{-4}$
Ruthenium (44)	Ru 97	S	$2X10^{-6}$	$1x10^{-2}$	$8X10^{-8}$	$4X10^{-4}$
		I	$2X10^{-6}$	$1X10^{-2}$	$6X10^{-8}$	$3X10^{-4}$
	Ru 103	S	$5X10^{-7}$	$2X10^{-3}$	$2X10^{-8}$	$8X10^{-5}$
		I	$8X10^{-8}$	$2X10^{-3}$	$3X10^{-9}$	$8X10^{-5}$
	Ru 105	S	$7X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$5X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
	Ru 106	S	$8X10^{-8}$	$4X10^{-4}$	$3X10^{-9}$	$1X10^{-5}$
		I	$6X10^{-9}$	$3X10^{-4}$	$2X10^{-10}$	$1X10^{-5}$
Samarium (62)	Sm 147	S	$7X10^{-11}$	$2X10^{-3}$	$2X10^{-12}$	$6X10^{-5}$
		I	$3X10^{-10}$	$2X10^{-3}$	$9X10^{-12}$	$7X10^{-5}$
	Sm 151	S	$6X10^{-8}$	$1X10^{-2}$	$2X10^{-9}$	$4X10^{-4}$
		I	$1X10^{-7}$	$1X10^{-2}$	$5X10^{-9}$	$4X10^{-4}$
	Sm 153	S	$5X10^{-7}$	$2X10^{-3}$	$2X10^{-8}$	$8X10^{-5}$
		I	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$8X10^{-5}$
Scandium (21)	Sc 46	S	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$4X10^{-5}$
		I	$2X10^{-8}$	$1X10^{-3}$	$8X10^{-10}$	$4X10^{-5}$
	Sc 47	S	$6X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$9X10^{-5}$
		I	$5X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$9X10^{-5}$
	Sc 48	S	$2X10^{-7}$	$8X10^{-4}$	$6X10^{-9}$	$3X10^{-5}$
		I	$1X10^{-7}$	$8X10^{-4}$	$5X10^{-9}$	$3X10^{-5}$
Selenium (34)	Se 75	S	$1X10^{-6}$	$9X10^{-3}$	$4X10^{-8}$	$3X10^{-4}$
		I	$1X10^{-7}$	$8X10^{-3}$	$4X10^{-9}$	$3X10^{-4}$
Silicon (14)	Si 31	S	$6X10^{-6}$	$3X10^{-2}$	$2X10^{-7}$	$9X10^{-4}$
		I	$1X10^{-6}$	$6X10^{-3}$	$3X10^{-8}$	$2X10^{-4}$
Silver (47)	Ag 105	S	$6X10^{-8}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$8X10^{-7}$	$3X10^{-4}$	$3X10^{-9}$	$1X10^{-4}$
	Ag 110 m	S	$2X10^{-8}$	$9X10^{-4}$	$7X10^{-9}$	$3X10^{-5}$
		I	$1X10^{-7}$	$9X10^{-4}$	$3X10^{-10}$	$3X10^{-5}$
	Ag 111	S	$3X10^{-7}$	$1X10^{-3}$	$1X10^{-8}$	$4X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$4X10^{-5}$
Sodium (11)	Na 22	S	$2X10^{-9}$	$1X10^{-3}$	$6X10^{-9}$	$4X10^{-5}$
		I	$9X10^{-9}$	$9X10^{-4}$	$3X10^{-10}$	$3X10^{-5}$
	Na 24	S	$1X10^{-6}$	$6X10^{-3}$	$4X10^{-8}$	$2X10^{-4}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
		I	$1X10^{-7}$	$8X10^{-4}$	$5X10^{-9}$	$3X10^{-5}$
Strontium (38)	Sr 85 m	S	$4X10^{-5}$	$2X10^{-1}$	$1X10^{-6}$	$7X10^{-3}$
		I	$3X10^{-5}$	$2X10^{-1}$	$1X10^{-6}$	$7X10^{-3}$
	Sr 85	S	$2X10^{-7}$	$3X10^{-3}$	$8X10^{-9}$	$1X10^{-4}$
		I	$1X10^{-7}$	$5X10^{-3}$	$4X10^{-9}$	$2X10^{-4}$
	Sr 89	S	$3X10^{-8}$	$3X10^{-4}$	$3X10^{-10}$	$3X10^{-6}$
		I	$4X10^{-8}$	$8X10^{-4}$	$1X10^{-9}$	$3X10^{-5}$
	Sr 90	S	$1X10^{-9}$	$1X10^{-5}$	$3X10^{-11}$	$3X10^{-7}$
		I	$5X10^{-9}$	$1X10^{-3}$	$2X10^{-10}$	$4X10^{-5}$
	Sr 91	S	$4X10^{-7}$	$2X10^{-3}$	$2X10^{-8}$	$7X10^{-5}$
		I	$3X10^{-7}$	$1X10^{-3}$	$9X10^{-9}$	$5X10^{-5}$
	Sr 92	S	$4X10^{-7}$	$2X10^{-3}$	$2X10^{-8}$	$7X10^{-5}$
		I	$3X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$6X10^{-5}$
Sulfur (16)	S 35	S	$3X10^{-7}$	$2X10^{-3}$	$9X10^{-9}$	$6X10^{-5}$
		I	$3X10^{-7}$	$8X10^{-3}$	$9X10^{-9}$	$3X10^{-4}$
Tantalum (73)	Ta 182	S	$4X10^{-8}$	$1X10^{-3}$	$1X10^{-9}$	$4X10^{-5}$
		I	$2X10^{-8}$	$1X10^{-3}$	$7X10^{-10}$	$4X10^{-5}$
Technetium (43)	Tc 96 m	S	$8X10^{-5}$	$4X10^{-1}$	$3X10^{-6}$	$1X10^{-2}$
		I	$3X10^{-5}$	$3X10^{-1}$	$1X10^{-6}$	$1X10^{-2}$
	Tc 96	S	$6X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$5X10^{-5}$
	Tc 97 m	S	$2X10^{-6}$	$1X10^{-2}$	$8X10^{-8}$	$4X10^{-4}$
		I	$2X10^{-7}$	$5X10^{-3}$	$5X10^{-9}$	$2X10^{-4}$
	Tc 97	S	$1X10^{-5}$	$5X10^{-2}$	$4X10^{-7}$	$2X10^{-3}$
		I	$3X10^{-7}$	$2X10^{-2}$	$1X10^{-8}$	$8X10^{-4}$
	Tc 99 m	S	$4X10^{-5}$	$2X10^{-1}$	$1X10^{-6}$	$6X10^{-3}$
		I	$1X10^{-5}$	$8X10^{-2}$	$5X10^{-7}$	$3X10^{-3}$
	Tc 99	S	$2X10^{-6}$	$1X10^{-2}$	$7X10^{-8}$	$3X10^{-4}$
		I	$6X10^{-8}$	$5X10^{-3}$	$2X10^{-9}$	$2X10^{-4}$
Tellurium (52)	Te 125 m	S	$4X10^{-7}$	$5X10^{-3}$	$1X10^{-8}$	$2X10^{-4}$
		I	$1X10^{-7}$	$3X10^{-3}$	$4X10^{-9}$	$1X10^{-4}$
	Te 127 m	S	$1X10^{-7}$	$2X10^{-3}$	$5X10^{-9}$	$6X10^{-5}$
		I	$4X10^{-8}$	$2X10^{-3}$	$1X10^{-9}$	$5X10^{-5}$
	Te 127	S	$2X10^{-6}$	$8X10^{-3}$	$6X10^{-8}$	$3X10^{-4}$
		I	$9X10^{-7}$	$5X10^{-3}$	$3X10^{-8}$	$2X10^{-4}$
	Te 129 m	S	$8X10^{-8}$	$1X10^{-3}$	$3X10^{-9}$	$3X10^{-5}$
		I	$3X10^{-8}$	$6X10^{-4}$	$1X10^{-9}$	$2X10^{-5}$
	Te 129	S	$5X10^{-6}$	$2X10^{-2}$	$2X10^{-7}$	$8X10^{-4}$
		I	$4X10^{-6}$	$2X10^{-2}$	$1X10^{-7}$	$8X10^{-4}$
	Te 131 m	S	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$6X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$6X10^{-9}$	$4X10^{-5}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

(See notes at end of appendix)

(Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
	Te 132	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
Terbium (65)	Tb 160	S	1×10^{-7}	1×10^{-3}	3×10^{-9}	4×10^{-5}
		I	3×10^{-8}	1×10^{-3}	1×10^{-9}	4×10^{-5}
Thallium (81)	Tl 200	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	1×10^{-6}	7×10^{-3}	4×10^{-8}	2×10^{-4}
	Tl 201	S	2×10^{-6}	9×10^{-3}	7×10^{-8}	3×10^{-4}
		I	9×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	Tl 202	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	2×10^{-7}	2×10^{-3}	8×10^{-9}	7×10^{-5}
	Tl 204	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	3×10^{-8}	2×10^{-3}	9×10^{-10}	6×10^{-5}
Thorium (90)	Th 227	S	3×10^{-10}	5×10^{-4}	1×10^{-11}	2×10^{-5}
		I	2×10^{-10}	5×10^{-4}	6×10^{-12}	2×10^{-5}
	Th 228	S	9×10^{-12}	2×10^{-4}	3×10^{-13}	7×10^{-6}
		I	6×10^{-12}	4×10^{-4}	2×10^{-13}	1×10^{-5}
	Th 230	S	2×10^{-12}	5×10^{-5}	8×10^{-14}	2×10^{-6}
		I	1×10^{-11}	9×10^{-4}	3×10^{-13}	3×10^{-5}
	Th 231	S	1×10^{-6}	7×10^{-3}	5×10^{-8}	2×10^{-4}
		I	1×10^{-6}	7×10^{-3}	4×10^{-8}	2×10^{-4}
	Th 232	S	3×10^{-11}	5×10^{-5}	1×10^{-12}	2×10^{-6}
		I	3×10^{-11}	1×10^{-3}	1×10^{-12}	4×10^{-5}
	Th natural	S	6×10^{-11}	6×10^{-5}	2×10^{-12}	2×10^{-6}
		I	6×10^{-11}	6×10^{-4}	2×10^{-12}	2×10^{-5}
	Th 234	S	6×10^{-8}	5×10^{-4}	2×10^{-9}	2×10^{-5}
		I	3×10^{-8}	5×10^{-4}	1×10^{-9}	2×10^{-5}
Thulium	Tm 170	S	4×10^{-8}	1×10^{-3}	1×10^{-9}	5×10^{-5}
		I	3×10^{-8}	1×10^{-3}	1×10^{-9}	5×10^{-5}
	Tm 171	S	1×10^{-7}	1×10^{-2}	4×10^{-9}	5×10^{-4}
		I	2×10^{-7}	1×10^{-2}	8×10^{-9}	5×10^{-4}
Tin (50)	Sn 113	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	9×10^{-5}
		I	5×10^{-8}	2×10^{-3}	2×10^{-9}	8×10^{-5}
	Sn 125	S	1×10^{-7}	5×10^{-4}	4×10^{-9}	2×10^{-5}
		I	8×10^{-8}	5×10^{-4}	3×10^{-9}	2×10^{-5}
Tungsten (Wolfram) (74)	W 181	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	1×10^{-7}	1×10^{-2}	4×10^{-9}	3×10^{-4}
	W 185	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
	W 187	S	4×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
Uranium (92)	U 230	S	3×10^{-10}	1×10^{-4}	1×10^{-11}	5×10^{-6}
		I	1×10^{-10}	1×10^{-4}	4×10^{-12}	5×10^{-6}
	U 232	S	1×10^{-10}	8×10^{-4}	3×10^{-2}	3×10^{-5}
		I	3×10^{-11}	8×10^{-4}	9×10^{-13}	3×10^{-5}
	U 233	S	5×10^{-10}	9×10^{-4}	2×10^{-11}	3×10^{-5}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope[1]		Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
		I	$1X10^{-10}$	$9X10^{-4}$	$4X10^{-12}$	$3X10^{-5}$
	U 234	S 4/	$6X10^{-10}$	$9X10^{-4}$	$2X10^{-11}$	$3X10^{-5}$
		I	$1X10^{-10}$	$9X10^{-4}$	$4X10^{-12}$	$3X10^{-5}$
	U 235	S 4/	$5X10^{-10}$	$8X10^{-4}$	$2X10^{-11}$	$3X10^{-5}$
		I	$1X10^{-10}$	$8X10^{-4}$	$4X10^{-12}$	$3X10^{-5}$
	U 236	S	$6X10^{-10}$	$1X10^{-3}$	$2X10^{-11}$	$3X10^{-5}$
		I	$1X10^{-10}$	$1X10^{-3}$	$4X10^{-12}$	$3X10^{-5}$
	U 238	S 4/	$7X10^{-11}$	$1X10^{-3}$	$3X10^{-12}$	$4X10^{-5}$
		I	$1X10^{-10}$	$1X10^{-3}$	$5X10^{-12}$	$4X10^{-5}$
	U 240	S	$2X10^{-7}$	$1X10^{-3}$	$8X10^{-9}$	$3X10^{-5}$
		I	$2X10^{-7}$	$1X10^{-3}$	$6X10^{-9}$	$3X10^{-5}$
	U natural	S 4/	$1X10^{-10}$	$1X10^{-3}$	$5X10^{-12}$	$3X10^{-5}$
		I	$1X10^{-10}$	$1X10^{-3}$	$5X10^{-12}$	$3X10^{-5}$
Vanadium (23)	V 48	S	$2X10^{-7}$	$9X10^{-4}$	$6X10^{-9}$	$3X10^{-5}$
		I	$6X10^{-8}$	$8X10^{-4}$	$2X10^{-9}$	$3X10^{-5}$
Xenon (54)	Xe 131 m	Sub	$2X10^{-5}$	------	$4X10^{-7}$	------
	Xe 133 m	Sub	$1X10^{-5}$	------	$3X10^{-7}$	------
	Xe 133	Sub	$1X10^{-6}$	------	$3X10^{-7}$	------
	Xe 135	Sub	$4X10^{-6}$	------	$1X10^{-7}$	------
Ytterbium (70)	Yb 175	S	$7X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
		I	$6X10^{-7}$	$3X10^{-3}$	$2X10^{-8}$	$1X10^{-4}$
Yttrium (39)	Y 90	S	$1X10^{-7}$	$6X10^{-4}$	$4X10^{-9}$	$2X10^{-5}$
		I	$1X10^{-7}$	$6X10^{-4}$	$3X10^{-9}$	$2X10^{-5}$
	Y 91 m	S	$2X10^{-5}$	$1X10^{-1}$	$8X10^{-7}$	$3X10^{-3}$
		I	$2X10^{-5}$	$1X10^{-1}$	$6X10^{-7}$	$3X10^{-3}$
	Y 91	S	$4X10^{-8}$	$8X10^{-4}$	$1X10^{-9}$	$3X10^{-5}$
		I	$3X10^{-8}$	$8X10^{-4}$	$1X10^{-9}$	$3X10^{-5}$
	Y 92	S	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$6X10^{-5}$
		I	$3X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$6X10^{-5}$
	Y 93	S	$2X10^{-7}$	$8X10^{-4}$	$6X10^{-9}$	$3X10^{-5}$
		I	$1X10^{-7}$	$8X10^{-4}$	$5X10^{-9}$	$3X10^{-5}$
Zinc (30)	Zn 65	S	$1X10^{-7}$	$3X10^{-3}$	$4X10^{-9}$	$1X10^{-4}$
		I	$6X10^{-8}$	$5X10^{-3}$	$2X10^{-9}$	$2X10^{-4}$
	Zn 69 m	S	$4X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$7X10^{-5}$
		I	$3X10^{-7}$	$2X10^{-3}$	$1X10^{-8}$	$6X10^{-5}$
	Zn 69	S	$7X10^{-6}$	$5X10^{-2}$	$2X10^{-7}$	$2X10^{-3}$
		I	$9X10^{-6}$	$5X10^{-2}$	$3X10^{-7}$	$2X10^{-3}$
Zirconium (40)	Zr 93	S	$1X10^{-7}$	$2X10^{-2}$	$4X10^{-9}$	$8X10^{-4}$
		I	$3X10^{-7}$	$2X10^{-2}$	$1X10^{-8}$	$8X10^{-4}$
	Zr 95	S	$1X10^{-7}$	$2X10^{-3}$	$4X10^{-9}$	$6X10^{-5}$
		I	$3X10^{-8}$	$2X10^{-3}$	$1X10^{-9}$	$6X10^{-5}$
	Zr 97	S	$1X10^{-7}$	$5X10^{-4}$	$4X10^{-9}$	$2X10^{-5}$
		I	$9X10^{-8}$	$5X10^{-4}$	$3X10^{-9}$	$2X10^{-5}$

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

/See notes at end of appendix/

Element (atomic number)	Isotope[1]	Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
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.	Sub	$1X10^{-6}$	------	$3X10^{-8}$	------
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.		$3X10^{-9}$	$9X10^{-5}$	$1X10^{-10}$	$3X10^{-6}$
Any single radionuclide not listed above, with decays by alpha emission or spontaneous fission.		6.0^{-13}	4.0^{-7}	$2X10^{-14}$	$3X10^{-8}$

APPENDIX A

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 A 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, and MPC_b, and MPC_c, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_a}{MPC_a} + \frac{C_b}{MPC_b} + \frac{C_c}{MPC_c} \leq 1$$

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

a. For purposes of Table I, Col. 1 --- $6X10^{-13}$

b. For purposes of Table I, Col. 2 --- $4X10^{-7}$

c. For purposes of Table II, Col. 1 --- $2X10^{-14}$

d. For purposes of Table II, Col. 2 --- $3X10^{-8}$

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 A 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 A are not present in the mixture, the concentration limit for the mixture is the lowest concentration limit specified in Appendix A for any radionuclide which is not known to be absent from the mixture; or,

c.

Element (atomic number) and isotope	Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
If it is known that Sr 90, I 125, I 126, I 129, I 131, (I 133, Table II only), Pb 210, Po 210, At 211, Ra 223, Ra 224, Ra 226, Ac 227, Ra 228, Th 230, Pa 231, Th 232, Th-nat, Cm 248, Cf 254, and Fm 256 are not present	------	$9X10^{-5}$	------	$3X10^{-6}$

c. Element (atomic number) and isotope	Table I Column 1 Air (uc/ml)	Table I Column 2 Water (uc/ml)	Table II Column 1 Air (uc/ml)	Table II Column 2 Water (uc/ml)
If it is known that Sr 90, I 125, I 126, I 129, (I 131, I 133, Table II only), Pb 210, Po 210, Ra 223, Ra 226, Ra 228, Pa 231, Th-nat, Cm 248, Cf 254, and Fm 256 are not present	------	$6X10^{-5}$	------	$2X10^{-6}$
If it is known that Sr 90, I 129, (I 125, I 126, I 131, Table II only), Pb 210, Ra 226, Ra 228, Cm 248, and Cf 254 are not present	------	$2X10^{-5}$	------	$6X10^{-7}$
If it is known that (I 129, Table II only), Ra 226, and Ra 228 are not present	------	$3X10^{-6}$	------	$1X10^{-7}$
If it is known that alpha-emitters and Sr 90, I 129, Pb 210, Ac 227, Ra 228, Pa 230, Pu 241, and Bk 249 are not present	$3X10^{-9}$	------	$1X10^{-10}$	------
If it is known that alpha-emitters and Pb 210, Ac 227, Ra 228, and Pu 241 are not present	$3X10^{-10}$	------	$1X10^{-11}$	------
If it is known that alpha-emitters and Ac 227 are not present	$3X10^{-11}$	------	$1X10^{-12}$	------
If it is known that Ac 227, Th 230, Pa 231, Pu 238, Pu 239, Pu 240, Pu 242, Pu 244, Cm 248, Cf 249 and Cf 251 are not present	$3X10^{-12}$	------	$1X10^{-13}$	------

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, Column 1, $1X10^{-10}$ uc/ml gross alpha activity; or $5X10^{-11}$ uc/ml natural uranium; or 75 micrograms per cubic meter of air natural uranium.

b. For purposes of Table II, Column 1, $3X10^{-12}$ uc/ml gross alpha activity; or 2×10^{-12} uc/ml natural uranium; or 3 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_a) to the concentration limit for that radionuclide specified in Table II of Appendix A (MPC_a) does not exceed 1/10, (i.e., $\frac{C_a}{MPC_a} = \frac{1}{10}$ and (b) the sum of such ratios for all nuclides considered as not present in the mixture does not exceed 1/4, (i.e., $\frac{C_a}{MPC_a} + \frac{C_b}{MPC_b} + \cdots = \frac{1}{4}$).

[1]Soluble (S); Insoluble (I).

[2]"Sub" means that values given are for submersion in a semi-spherical infinite cloud of airborne material.

[3]These radon concentrations are appropriate for protection from radon-222 combined withits 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 1.3×10^5 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.

[4]For soluble mixtures 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 $8x10^{-3}$ SA uC[illegible]l, 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^{-7} curies per gram U. The specific activity for other mixtures of U-238, U-235 and U-234, if not known, shall be:

$SA = 3.6 \times 10^{-7}$ curies/gram U — U-depleted

$SA = (0.4 + 0.38\ E + 0.0034\ E^2)\ 10\text{-}6$ — $E \geq 0.72$

where E is the percentage by weight of U-235, expressed as percent.

APPENDIX B
WASTE DISPOSAL BURIAL LIMITS

Material	Micro-curies
Americium 241	0.01
Antimony 122	100
Antimony 124	10
Antimony 125	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 115	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 135	10
Cesium 136	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 152 9.2h	100
Europium 152 13 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 135	10
Iridium 192	10
Iridium 194	100
Iron 55	100
Iron 59	10
Krypton 85	100
Krypton 87	10
Lanthanum 140	10
Lutetium 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 59	100
Nickel 63	10
Nickel 65	100
Niobium 93m	10
Niobium 95	10
Niobium 97	10
Osmium 185	10
Osmium 191m	100
Osmium 191	100
Osmium 193	100
Palladium 103	100
Palladium 109	100
Phosphorus 32	10
Platinum 191	100
Platinum 193m	100
Platinum 193	100
Platinum 197m	100
Platinum 197	100
Plutonium 239	0.01
Polonium 210	0.1
Potassium 42	10
Praseodymium 142	100
Praseodymium 143	100
Promethium 147	10
Promethium 149	10
Radium 226	0.01
Rhenium 186	100
Rhenium 188	100
Rhodium 103m	100
Rhodium 105	100
Rubidium 86	10
Rubidium 87	10
Ruthenium 97	100
Ruthenium 103	10
Ruthenium 105	10
Ruthenium 106	1
Samarium 151	10
Samarium 153	100
Scandium 46	10
Scandium 47	100
Scandium 48	10
Selenium 75	10
Silicon 31	100
Silver 105	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

Material	Microcuries	Material	Microcuries
Thallium 202	100	Yttrium 91	10
Thallium 204	10	Yttrium 92	100
Thorium (natural)[1]	100	Yttrium 93	100
Thulium 170	10	Zinc 65	10
Thulium 171	10	Zinc 69m	100
Tin 113	10	Zinc 69	1,000
Tin 125	10	Zirconium 93	10
Tungsten 181	10	Zirconium 95	10
Tungsten 185	10	Zirconium 97	10
Tungsten 187	100		
Uranium (natural)[2]	100	Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition..	0.01
Uranium 233	0.01		
Uranium 234			
Uranium 235	0.01		
Vanadium 48	10	Any radionuclide other than alpha emitting radionuclides not listed above or mixtures of beta emitters of unknown composition.....	0.1
Xenon 131m	1,000		
Xenon 133	100		
Xenon 135	100		
Ytterbium 175	100		
Yttrium 90	10		

NOTE: For purposes of sections A.3.3, A.4.3 and A.4.4, 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.

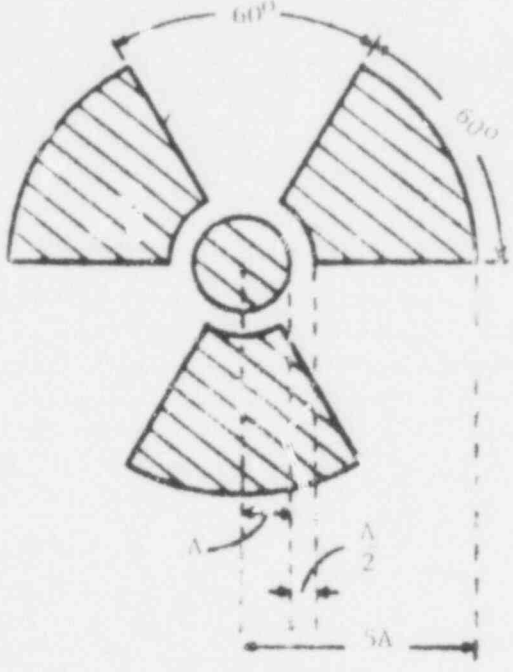
APPENDIX B

EXAMPLE: For purposes of section A.4.4 if a particular batch contains 2,000 uc of Au^{198} and 25,000 uc of C^{14}, it may also include not more than 3,000 uc of I^{131}. This limit was determined as follows:

$$\frac{2{,}000\text{uc}}{10{,}000\text{uc}}\ Au^{198} + \frac{25{,}000\text{uc}}{50{,}000\text{uc}}\ C^{14} + \frac{3{,}000\text{uc}}{10{,}000\text{uc}}\ I^{131} = 1$$

The denominator in each of the above ratios was obtained by multiplying the figure in the table by 1,000 as provided in section A.304.

APPENDIX C



RADIATION SYMBOL

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

2. Background is to be yellow.

APPENDIX D
TRANSPORT GROUPING OF RADIONUCLIDES

Element[1]	Radionuclide[2]	Group
Actinium (89)	Ac-227	I
	Ac-228	I
Americium (95)	Am-241	I
	Am-243	I
Antimony (51)	Sb-122	IV
	Sb-124	III
	Sb-125	III
Argon (18)	Ar-37	VI
	Ar-41	II
	Ar-41 (uncompressed)[3]	V
Arsenic (33)	As-73	IV
	As-74	IV
	As-76	IV
	As-77	IV
Astatine (85)	At-211	III
Barium (56)	Ba-131	IV
	Ba-133	II
	Ba-140	III
Berkelium (97)	Bk-249	I
Beryllium (4)	Be-7	IV
Bismuth (83)	Bi-206	IV
	Bi-207	III
	Bi-210	II
	Bi-212	III
Bromine (35)	Br-82	IV
Cadmium (48)	Cd-109	IV
	Cd-115m	III
	Cd-115	IV
Calcium (20)	Ca-45	IV
	Ca-47	IV
Californium (98)	Cf-249	I
	Cf-250	I
	Cf-252	I
Carbon (6)	C-14	IV
Cerium (58)	Ce-141	IV
	Ce-143	IV
	Ce-144	III
Cesium (55)	Cs-131	IV
	Cs-134m	III
	Cs-134	III
	Cs-135	IV
	Cs-136	IV
	Cs-137	III
Chlorine (17)	Cl-36	III
	Cl-38	IV
Chromium (24)	Cr-51	IV

Element [1]	Radionuclide [2]	Group
Cobalt (27)	Co-56	III
	Co-57	IV
	Co-58m	IV
	Co-58	IV
	Co-60	III
Copper (29)	Cu-64	IV
Curium (96)	Cm-242	I
	Cm-243	I
	Cm-244	I
	Cm-245	I
	Cm-246	I
Dysprosium (66)	Dy-154	III
	Dy-165	IV
	Dy-166	IV
Erbium (68)	Er-169	IV
	Er-171	IV
Europium (63)	Eu-150	III
	Eu-152m	IV
	Eu-152	III
	Eu-154	II
	Eu-155	IV
Fluorine (9)	F-18	IV
Gadolinium (64)	Gd-153	IV
	Gd-159	IV
Gallium (31)	Ga-67	III
	Ga-72	IV
Germanium (32)	Ge-71	IV
Gold (79)	Au-193	III
	Au-194	III
	Au-195	III
	Au-196	IV
	Au-198	IV
	Au-199	IV
Hafnium (72)	Hf-181	IV
Holmium (67)	Ho-166	IV
Hydrogen (1)	H-3 (see tritium)	
Indium (49)	In-113m	IV
	In-114m	III
	In-115m	IV
	In-115	IV
Iodine (53)	I-124	III
	I-125	III
	I-126	III
	I-129	III
	I-131	III
	I-132	IV
	I-133	III
	I-134	IV
	I-135	IV

Element [1]	Radionuclide [2]	Group
Iridium (77)	Ir-190	IV
	Ir-192	III
	Ir-194	IV
Iron (26)	Fe-55	IV
	Fe-59	IV
Krypton (36)	Kr-85m	III
	Kr-85m (uncompressed) [3]	V
	Kr-85	III
	Kr-85 (uncompressed) [3]	VI
	Kr-87	II
	Kr-87 (uncompressed) [3]	V
Lanthanum (57)	La-140	IV
Lead (32)	Pb-203	IV
	Pb-210	II
	Pb-212	II
Lutetium (71)	Lu-172	III
	Lu-177	IV
Magnesium (12)	Mg-28	III
Manganese (25)	Mn-52	IV
	Mn-54	IV
	Mn-56	IV
Mercury (80)	Hg-197m	IV
	Hg-197	IV
	Hg-203	IV
Mixed fission products (MFP)		II
Molybdenum (42)	Mo-99	IV
Neodymium (60)	Nd-147	IV
	Nd-149	IV
Neptunium (93)	Np-237	I
	Np-239	I
Nickel (28)	Ni-56	III
	Ni-59	IV
	Ni-63	IV
	Ni-65	IV
Niobium (41)	Nb-93m	IV
	Nb-95	IV
	Nb-97	IV
Osmium (76)	Os-185	IV
	Os-191m	IV
	Os-191	IV
	Os-193	IV
Palladium (46)	Pd-103	V
	Pd-109	IV
Phosphorus (15)	P-32	IV
Platinum (78)	Pt-191	IV
	Pt-193	IV
	Pt-193m	IV
	Pt-197m	IV
	Pt-197	IV

Element [1]	Radionuclide [2]	Group
Plutonium (94)	Pu-238 (F)	I
	Pu-239 (F)	I
	Pu-240	I
	Pu-241 (F)	I
	Pu-242	I
Polonium (84)	Po-210	I
Potassium (19)	K-42	IV
	K-43	III
Praseodymium (59)	Pr-142	IV
	Pr-143	IV
Promethium (61)	Pm-147	IV
	Pm-149	IV
Protactinium (91)	Pa-230	I
	Pa-231	I
	Pa-233	II
Radium (88)	Ra-223	II
	Ra-224	II
	Ra-226	I
	Ra-228	I
Radon (86)	Rn-220	IV
	Rn-222	II
Rhenium (75)	Re-183	IV
	Re-186	IV
	Re-187	IV
	Re-188	IV
	Re-Natural	IV
Rhodium (45)	Rh-103m	IV
	Rh-105	IV
Rubidium (37)	Rb-86	IV
	Rb-87	IV
	Rb-Natural	IV
Ruthenium (44)	Ru-97	IV
	Ru-103	IV
	Ru-105	IV
	Ru-106	III
Samarium (62)	Sm-145	III
	Sm-147	III
	Sm-151	IV
	Sm-153	IV
Scandium (21)	Sc-46	III
	Sc-47	IV
	Sc-48	IV
Selenium (34)	Se-75	IV
Silicon (14)	Si-31	IV
Silver (47)	Ag-105	IV
	Ag-110m	III
	Ag-111	IV
Sodium (11)	Na-22	III
	Na-24	IV

Element[1/]	Radionuclide[2/]	Group
Strontium(38)	Sr-85m	IV
	Sr-85	IV
	Sr-89	III
	Sr-90	II
	Sr-91	III
	Sr-92	IV
Sulfur(16)	S-35	IV
Tantalum(73)	Ta-182	III
Technetium(43)	Tc-96m	IV
	Tc-96	IV
	Tc-97m	IV
	Tc-97	IV
	Tc-99m	IV
	Tc-99	IV
Tellurium(52)	Te-125m	IV
	Te-127m	IV
	Te-127	IV
	Te-129m	III
	Te-129	IV
	Te-131m	III
	Te-132	IV
Terbium(65)	Tb-160	III
Thallium(81)	Tl-200	IV
	Tl-201	IV
	Tl-202	IV
	Tl-204	III
Thorium(90)	Th-227	II
	Th-228	I
	Th-230	I
	Th-231	I
	Th-232	III
	Th-234	II
	Th-Natural	III
Thulium(69)	Tm-168	III
	Tm-170	III
	Tm-171	IV
Tin(50)	Sn-113	IV
	Sn-117m	III
	Sn-121	III
	Sn-125	IV
Tritium(1)	H-3	IV
	H-3(as a gas, as luminous paint, or adsorbed on solid material)	VII
Tungsten(74)	W-181	IV
	W-185	IV
	W-187	IV

Element 1/	Radionuclide 2/	Group
Uranium (92)	U-230	II
	U-232	I
	U-233 (F)	II
	U-234	II
	U-235 (F)	III
	U-236	II
	U-238	III
	U-Natural	III
	U-Enriched (F)	III
	U-Depleted	III
Vanadium (23)	V-48	IV
	V-49	III
Xenon (54)	Xe-125	III
	Xe-131m	III
	Xe-131m (uncompressed) 3/	V
	Xe-133	III
	Xe-133 (uncompressed) 3/	VI
	Xe-135	II
	Xe-135 (uncompressed) 3/	V
Ytterbium (70)	Yb-175	IV
Yttrium (39)	Y-88	III
	Y-90	IV
	Y-91m	III
	Y-91	III
	Y-92	IV
	Y-93	IV
Zinc (30)	Zn-65	IV
	Zn-69m	IV
	Zn-69	IV
Zirconium (40)	Zr-93	IV
	Zr-95	III
	Zr-97	IV

1/ Atomic number shown in parentheses.
2/ Atomic mass number shown after the element symbol.
3/ Uncompressed means at a pressure not exceeding one atmosphere.
m Metastable state.
(F) Fissile material.

APPENDIX E

TESTS FOR SPECIAL FORM LICENSED MATERIAL

1. Free Drop - A free drop through a distance of 30 feet onto a flat essentially unyielding horizontal surface, striking the surface in such a position as to suffer maximum damage.

2. Percussion - Impact of the flat circular end of a 1 inch diameter steel rod weighing 3 pounds, dropped through a distance of 40 inches. The capsule or material shall be placed on a sheet of lead, of hardness number 3.5 to 4.5 on the Vickers scale, and not more than 1 inch thick, supported by a smooth essentially unyielding surface.

3. Heating - Heating in air to a temperature of 1,475°F and remaining at that temperature for a period of 10 minutes.

4. Immersion - Immersion for 24 hours in water at room temperature. The water shall be at pH6 - pH8, with a maximum conductivity of 10 micromhos per centimeter.

RHODE ISLAND RULES AND REGULATIONS

FOR THE

CONTROL OF RADIATION

PART B

REGISTRATION OF X-RAY EQUIPMENT FACILITIES AND SERVICES

Adopted 2 June 1978

PART B

REGISTRATION OF X-RAY EQUIPMENT FACILITIES AND SERVICES

B.1 PURPOSE AND SCOPE

B.1.1 This part requires the registration of x-ray equipment facilities and the registration of persons providing x-ray equipment installation, servicing, and/or services. For purposes of this part, particle accelerator facilities, whether used primarily for x-ray production or other purposes, shall be considered x-ray equipment facilities.

B.1.2 For purposes of part B of these regulations, "facility" means the location at which one or more x-ray systems are installed and/or located within one building or vehicle, and are under the same administrative control.

B.1.3 In addition to the requirements of this part, all registrants are subject to the applicable provisions of other parts of these regulations.

B.2 EXEMPTIONS

B.2.1 Electronic equipment that produces radiation incidental to its operation or other purposes is exempt from the registration and certification requirements of this part, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem per hour at 5 cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

B.2.2 X-ray equipment while in transit or storage incident thereto is exempt from the requirements of this part.

B.2.3 Domestic television receivers are exempt from the requirements of this part.

B.3 APPLICATION FOR REGISTRATION OF X-RAY EQUIPMENT FACILITIES

Each person who owns or possesses and administratively controls an x-ray equipment facility, unless specifically exempted in B.2, shall:

B.3.1 Apply for registration of such facility with the Agency within 45 days following the effective date of these regulations or thereafter prior to the operation of an x-ray equipment facility. Application for registration shall be completed on forms furnished by the Agency and shall contain all the information required by the form and accompanying instructions. The specific confines of the x-ray equipment shall, if the Agency determines necessary, be indicated by a plan drawn to scale.

B.3.2 Designate on the application form an individual to be responsible for radiation protection.

B.3.3

B.3.3 Prohibit any person from furnishing x-ray equipment servicing or services as described in B.4.4 of this part to his x-ray equipment facility until such person provides evidence that he is registered with the Agency as a provider of services in accordance with subpart B.4 of these regulations.

B.4 APPLICATION FOR REGISTRATION OF SERVICING AND SERVICES

B.4.1 Each person who is engaged in the business of installing or offering to install x-ray equipment or is engaged in the business of furnishing or offering to furnish x-ray equipment servicing or services in this State, to an Agency registrant, shall apply for registration of such services with the Agency within 45 days following the effective date of these regulations or thereafter prior to furnishing or offering to furnish any such services.

B.4.2 Application for Registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions.

B.4.3 Each person applying for registration under this part shall specify:

(a) That he has read and understands the requirements of these regulations; and

(b) The training and experience that qualify him to discharge the services for which he is applying for registration.

B.4.4 For the purpose of this subpart, services may include but shall not be limited to:

(a) Installation and/or servicing of x-ray equipment and associated components,

(b) Calibration of x-ray equipment or radiation measurement instruments or devices,

(c) Radiation protection or health physics consultations or surveys, and

(d) Personnel dosimetry services.

B.4.5 Persons offering the services described in B.4.4 shall not provide such services to any operational x-ray equipment facility in this state until such facility provides evidence that it has been registered with the Agency in accordance with subpart B.3 of these regulations. Persons providing the services described in B.4.4 to a preoperational x-ray facility shall inform the facility of the registration requirements of these regulations.

B.5 CERTIFICATE OF REGISTRATION

B.5.1 Persons who have applied for registration within the first 45 days following the effective date of these regulations, and whose application meets the requirements for registration, shall, upon payment of the registration fee, be issued a Certificate of Registration effective 90 days after the effective date of these regulations. Thereafter, no person who is required to be registered under this part shall operate an x-ray equipment facility or service without a valid Certificate of Registration.

B.5.2 The Agency may incorporate in the Certificate of Registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of x-ray equipment as it deems appropriate or necessary.

B.5.3 A current Certificate of Registration or legible copy thereof shall be posted conspicuously at each registered facility.

B.5.4 Except as provided by B.5.6, each Certificate of Registration shall expire at the end of the day on the date stated therein.

B.5.5 Application for renewal of registration shall be filed in accordance with subpart B.3 or B.4 of this part.

B.5.6 In any case in which a registrant not less than 30 days prior to the expiration of his existing Certificate of Registration has filed an application in proper form for renewal, and has remitted the renewal fee, such existing Certificate of Registration shall not expire until the application status has been finally determined by the Agency.

B.6 REPORT OF CHANGES

The registrant shall notify the Agency in writing before making any change which would render the information contained in the Application for Registration and/or the Certificate of Registration no longer accurate. In the case of disposition of an x-ray system, such notification should specify the recipient of the system. In the case of modifications involving a structural change, or the addition or relocation of an x-ray system, the Agency may require the registrant to submit the information contained in Appendix A of this part. The Agency may also require that the information submitted be reviewed and approved by a qualified expert who is registered with the Agency in accordance with the provisions of subpart B.4.[1]

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[1]Prospective registrants are urged to notify the Agency of their intent to construct an x-ray equipment facility and to submit the information contained in Appendix A of this part prior to constructing the facility in order to avoid possible additional expense to the registrant in meeting Agency requirements.

B.7 APPROVAL NOT IMPLIED

No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of subpart B.3 or B.4 of this part and no person shall state or imply that any activity under such registration has been approved by the Agency.

B.8 ASSEMBLER AND/OR TRANSFER OBLIGATION

B.8.1 Any person who sells, leases, transfers, lends, disposes, assembles, or installs x-ray equipment in this State shall notify the Agency within 90 days of:

(a) The name and address of persons who have received this equipment.

(b) The manufacturer, model, and serial number of each x-ray system transferred; and

(c) The date of transfer of each x-ray system.

(d) In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-ray Standard (21 CFR 1020.30 (d)) shall be submitted to the Agency within 90 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

B.8.2 No person shall make, sell, lease, transfer, lend, assemble, or install x-ray systems or the supplies used in connection with such systems unless such supplies and equipment when properly placed in operation and used in this State shall meet the requirements of these regulations.

B.9 WAIVER OF REGISTRATION FOR TEMPORARY USE

B.9.1 Whenever any x-ray system is to be brought into the State, for any temporary use, the person proposing to bring such system into the State shall give written notice to the Agency at least two (2) working days before such machine is to be used in the State. The notice shall include the type of x-ray system; the nature, duration, and scope of use; and the exact location(s) where the x-ray system is to be used. Upon receipt of such notification, the Agency shall determine whether a waiver of registration will be granted.

B.9.2 In addition, the out-of-State person shall:

(a) Comply with all applicable regulations of the Agency; and

(b) Supply the Agency with such other information as the Agency may reasonably request.

B.10 REGISTRATION FEES

In accordance with authority granted to the Agency in Chapter 23-1.3-5 of the General Laws of Rhode Island, registration fees are payable to the Treasurer, State of Rhode Island by persons applying for registration. A current schedule of fees is available from the Agency. Upon approval of the application, the Agency will notify the applicant of the correct fee which is due. A Certificate of Registration will not be issued or renewed until the correct fee has been remitted. Fees which remain unpaid beyond the expiration date of the current Certificate of Registration may result in suspension of registration.

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the Agency to review plans for radiation shielding, the following information shall be submitted:

1. The plans shall show as a minimum, the following:

   (a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

   (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

   (c) The dimensions of the room(s) concerned.

   (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

   (e) The make and model of the x-ray equipment and the maximum technique factors.

   (f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the x-ray system(s).

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report including all basic assumptions used, shall be submitted with the plans.

RHODE ISLAND RULES AND REGULATIONS

FOR THE

CONTROL OF RADIATION

PART C

LICENSING OF RADIOACTIVE MATERIAL AND USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

Adopted 5 February 1979

PART C
LICENSING OF RADIOACTIVE MATERIAL AND USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

C.1 GENERAL PROVISIONS

C.1.1 Purpose and Scope.

(a) This part provides for the licensing of radioactive material and use of sealed radioactive sources in the healing arts. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this part or as otherwise provided in this part.

(b) In addition to the requirements of this part, all licensees are subject to the requirements of part A, of these regulations and licensees engaged in industrial radiographic operations are subject to the requirements of part E.

C.2 EXEMPTIONS

C.2.1 Source Material.

(a) Any person is exempt from this part to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

(c) Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers:

(1) Any quantities of thorium contained in

(i) incandescent gas mantles,

(ii) vacuum tubes,

(iii) welding rods,

(iv) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

C.2.1(c) (1) (v)

(v) Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium,

(vi) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

(vii) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

(2) Source material contained in the following products:

(i) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

(ii) glassware, glass enamel and glass enamel frit containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction, or

(iii) piezoelectric ceramic containing not more than 2 percent by weight source material;

(3) Photographic film, negatives, and prints containing uranium or thorium;

(4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing or any such product or part;

(5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that

(i) the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR part 40,

(ii) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM", [1] and

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[1] The requirements specified in C.2.1(c)(5)(ii) and (iii) need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the regulations.

(iii) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED,"[1] and

(iv) this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

(6) Uranium used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM" and which meets the specifications for containers for radioactive material prescribed in Section 173.394 or 173.395 of 49 CFR Part 173 of U.S. Department of Transportation regulations;

(7) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either

(i) the shaping, grinding, or polishing of such lenses or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

(ii) the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

(8) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

(9) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that

(i) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and

(ii) the thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

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[1]The requirements specified in C.2.1 (c) (5) (ii) and (iii) need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the regulations.

C.2.1 (d)

(d) The exemptions in C.2.1 (c) do not authorize the manufacture of any of the products described.

C.2.2 Radioactive Material Other Than Source Material.

(a) Exempt Concentrations.

(1) Except as provided in C.2.2 (a) (2), any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material in concentrations not in excess of those listed in Appendix A.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under C.2.2 (a) (1) or equivalent regulations of the U. S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued pursuant to C.5.5 (a) or the general license provided in C.6.1.

(b) Exempt Quantities.

(1) Except as provided in C.2.2 (b) (2) and (3) any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Appendix B of this part.

(2) This paragraph does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(3) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under C.2.2 (b) or equivalent regulations of the U. S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 or by the Agency pursuant to C.5.5 (b) which license states that the radioactive material may be transferred by the licensee to persons exempt under C.2.2 (b) or the equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State.

(c) Exempt Items.

(1) Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any

C.2.2 (c) (1)

person is exempt from these regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:[2]

(i) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(a) 25 millicuries of tritium per timepiece,
(b) 5 millicuries of tritium per hand,
(c) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial),
(d) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece,
(e) 20 microcuries of promethium-147 per watch hand or, 40 microcuries of promethium-147 per other timepiece hand,
(f) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial),
(g) The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(1) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface

(2) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface

(3) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(h) one microcurie of radium-226 per timepiece in time pieces acquired prior to the effective date of these regulations.

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[2] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U. S. Nuclear Regulatory Commission, Washington, D. C. 20555.

(ii) Lock illuminators containing not more than 15 millicuries of tritium or not more than 2 millicuries of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

(iii) Precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part.

(iv) Automobile shift quadrants containing not more than 25 millicuries of tritium.

(v) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas.

(vi) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat.

(vii) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of byproduct material:

(a) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;
(b) 1 microcurie of cobalt-60;
(c) 5 microcuries of nickel-63;
(d) 30 microcuries of krypton-85;
(e) 5 microcuries of cesium-137;
(f) 30 microcuries of promethium-147;

And provided further, that the levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[3]

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[3] For purposes of C.2.2(c)(1)(vii), "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

C.2.2 (c) (1) (viii)

(viii) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material not exceeding the applicable quantity set forth in Appendix B of this part.

(ix) Spark gap irradiators containing not more than 1 microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons(11.4 liters) per hour.

(2) Self-luminous products containing radioactive material.

(i) Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U. S. Nuclear Regulatory Commission pursuant to section 32.22 of 10 CFR part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in C.2.2 (c) (2) does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

(ii) Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie of radium-226 which were acquired prior to the effective date of these regulations.

(3) Gas and aerosol detectors containing radioactive material.

(i) Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a

specific license issued by the U.S. Nuclear Regulatory Commission[2] pursuant to section 32.26 of 10 CFR part 32, or a Licensing State, pursuant to C.5.5 (c), which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(ii) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under C.2.2 (c) (3) (i), provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirement of C.5.5 (c).

(iii) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under C.2.2 (c) (3) (i), provided that the device is labeled in accordance with the specific license authorizing distribution and provided further that they meet the requirements of C.5.5 (c).

(4) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in sections 32.16 and 32.17 of 10 CFR part 32 of the regulations of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

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[2]Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other produce containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

C.3 LICENSES

C.3.1 Types of Licenses. Licenses for radioactive materials are of two types: general and specific.

(a) General licenses provided in this part are effective without the filing of applications with the Agency or the issuance of licensing documents to the particular persons, although the filing of a certificate with the Agency may be required by the particular general license. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

(b) Specific licenses require the submission of an application to the Agency and the issuance of a licensing document by the Agency. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document.

C.4 GENERAL LICENSES

C.4.1 General Licenses - Source Material.

(a) A general license is hereby issued authorizing use and transfer of not more than 15 pounds of source material at any one time by persons in the following categories:

(1) Pharmacists using the source material solely for the compounding of medicinals;

(2) Physicians using the source material for medicinal purposes;

(3) Persons receiving possession of source material from pharmacists and physicians in the form of medicinals or drugs;

(4) Commercial and industrial firms, and research, educational, and medical institutions, and State and local governmental agencies for research, development, educational, commercial or operational purposes.

And provided, that no such person shall, pursuant to this general license, receive more than a total of 150 pounds of source material in any one calendar year.

(b) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in C.4.1 (a) are exempt from the provisions of Subparts A.1 - A.6 of these regulations to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this part.

(c) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

(d) Depleted Uranium in Industrial Products and Devices.

(1) A general license is hereby issued to receive, acquire, possess, use or transfer, in accordance with the provisions of C.4.1 (d)(2), (3), (4) and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in C.4.1(d)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to C.5.5(m) or in accordance with a specific license issued to the manufacturer by the U. S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U. S. Nuclear Regulatory Commission or an Agreement State.

(3) (i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by C.4.1(d)(1) shall file Agency Form GEN-1 "Registration Certificate - Use of Depleted Uranium Under General License," with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on Agency Form GEN-1 the following information and such other information as may be required by that form:

(a) name and address of the registrant;

(b) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in C.4.1 (d)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(c) name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedure identified in C.4.1(d)(3)(i)(b).

C.4.1 (d) (3) (ii)

(ii) The registrant possessing or using depleted uranium under the general license established by C.4.1(d)(1) shall report in writing to the Agency any changes in information furnished by him in Agency Form GEN-1 "Registration Certificate-Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by C.4.1(d)(1):

(i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

(ii) Shall not abandon such depleted uranium.

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of C.5.14. In the case where the transferee receives the depleted uranium pursuant to the general license established by C.4.1(d)(1), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form GEN-1. In cases where the transferee receives the depleted uranium pursuant to a general license contained in the U. S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.4.1(d)(1), the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form GEN-1 accompanied by a note explaining that use of the product or device is regulated by the U. S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this regulation.

(iv) Within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer.

(v) Shall not export such depleted uranium except in accordance with a license issued by the U. S. Nuclear Regulatory Commission pursuant to Sections 40.23 and 40.33 of 10 CFR Part 40.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by C.4.1(d)(1) is exempt from the requirements of A.1-A.6 of these regulations with respect to the depleted uranium covered by that general license.

C.4.2 General Licenses - Radioactive Material other than Source Material.

(a) Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U. S. Nuclear Regulatory Commission for use pursuant to section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of C.2.2(a) (2), C.5.7, C.5.14, C.5.15, C.7.1 and part A[4].

(1) Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device.

(2) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.

(b) Certain Measuring, Gauging and Controlling Devices.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of C.4.2 (b) (2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in C.4.2 (b) (1) applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to C.5.5 (d) or in accordance with the specifications contained in a specific license issued by the U. S. Nuclear Regulatory Commission, an

[4] Attention is directed particularly to the provisions of part A of these regulations which relate to the labeling of containers.

C.4.2 (b) (3) (iv)

(iv) shall maintain records showing compliance with the requirements of C.4.2 (b) (3) (ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by C.4.2 (b) (3) (ii) shall be maintained for 1 year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the on/off mechanism and indicator required by C.4.2 (b) (3) shall be maintained for 1 year after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by C.4.2 (b) (3) (iii) shall be maintained for a period of 2 years from the date of the recorded event or until the device is transferred or disposed of;

(v) upon the occurrence of a failure of or damage to, any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing state to repair such devices or dispose of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency a report containing a brief description of the event and the remedial action taken;

(vi) shall not abandon the device containing radioactive material;

(vii) except as provided in C.4.2 (b) (3) (viii), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the U. S. Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Agency a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(viii) shall transfer the device to another general licensee only:

(a) where the device remains in use at a particular location. In such case the transferor shall give the transferee a

copy of this regulation and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Agency and the transferee; or

(b) where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee;

(ix) shall comply with the provisions of A.5.2 and A.5.3 of these regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of A.1 - A.6 of these regulations.

(4) The general license in C.4.2 (b) (1) does not authorize the manufacture of devices containing radioactive material.

(5) The general license provided in C.4.2 (b) (1) is subject to the provisions of A.7, C.5.7, C.5.14, C.5.15 and C.7.1 of these regulations.

(c) Luminous Safety Devices for Aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(i) each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147; and

(ii) each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in section 32.53 of 10 CFR part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in C.4.2 (c) (1) are exempt from the requirements of A.1-A.6 of these regulations except that they shall comply with the provisions of A.5.2 and A.5.3

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

C.4.2 (c) (4)

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of A.7, C.5.7, C.5.14, C.5.15 and C.7.1 of these regulations.

(d) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

(e) Calibration and Reference Sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of C.4.2 (e) (4) and (5), americium-241 in the form of calibration or reference sources:

(i) Any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material; and

(ii) Any person who holds a specific license issued by the U. S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of C.4.2 (e) (4) and (5) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of C.4.2 (e) (4) and (5) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use and transfer radioactive material.

(4) The general licenses in C.4.2 (e) (1), (2) and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the source by the U. S. Nuclear Regulatory Commission pursuant to section 32.57 of 10 CFR Part 32 or section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Agency, any Agreement State or Licensing State pursuant to

licensing requirements equivalent to those contained in section 32.57 of 10 CFR Part 32 or section 70.39 of 10 CFR Part 70 of the regulations of the U.S. Nuclear Regulatory Commission.

(5) The general licenses provided in C.4.2 (e) (1), (2) and (3) are subject to the provisions of part A, C.5.7, C.5.14, C.5.15, and C.7.1 of these regulations. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

(i) shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium-241, 5 microcuries of plutonium, and 5 microcuries of radium-226 in such sources;

(ii) shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements as appropriate or a substantially similar statement which contains the information called for in one of the following statements as appropriate:

(a) The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM)[6] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer of importer

(b) The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of any Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

[6]Showing only the name of the appropriate material

(iii) shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Agency, the U. S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;

(iv) shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(f) Medical Diagnostic Uses[7/8]

(1) A general license is hereby issued to any physician to receive, possess, transfer, or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of C.4.2 (f) (2), (3), and (4), the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued pursuant to C.5.5 (g) by the Agency, the U. S. Nuclear Regulatory Commission, any Agreement State or a Licensing State authorizing distribution to persons generally licensed pursuant to this paragraph or its equivalent:

(i) Iodine-131 as sodium iodide ($Na^{131}I$) for measurement of thyroid uptake;

(ii) Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(iii) Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(iv) Cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;

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[7] C.5.5 (g) requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical.

[8] The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

C.4.2 (f) (1) (v)

(v) Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;

(vi) Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin; and

(vii) Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.

(2) No physician shall receive, possess, use, or transfer radioactive material pursuant to the general license established by C.4.2 (f) (1) until he has filed Agency Form GEN-2 "Certificate - Medical Use of Radioactive Material Under General License" with the Agency and received from the Agency a validated copy of the form with certification number assigned. The generally licensed physician shall furnish on Agency Form GEN-2 the following information and such other information as may be required by that form:

(i) Name and address of the generally licensed physician;

(ii) A statement that the generally licensed physician is a duly licensed physician (authorized to dispense drugs) in the practice of medicine in this State; and

(iii) A statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of C.4.2 (f) and that he is competent in the use of such instruments.

(3) A physician who receives, possesses, or uses a pharmaceutical containing radioactive material pursuant to the general license established by C.4.2 (f) (1) shall comply with the following:

(i) He shall not possess at any one time, pursuant to the general license in C.4.2 (f) (1) more than

(a) 200 microcuries of iodine-131,
(b) 200 microcuries of iodine-125,
(c) 5 microcuries of cobalt-57,
(d) 5 microcuries of cobalt-58,
(e) 5 microcuries of cobalt-60, and
(f) 200 microcuries of chromium-51;

(ii) He shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;

C.4.2 (f) (3) (iii)

(iii) he shall use the pharmaceutical only for the uses authorized by C.4.2 (f) (1);

(iv) he shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and

(v) he shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U. S. Nuclear Regulatory Commission, any Agreement State or Licensing State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(4) The generally licensed physician possessing or using radioactive material under the general license of C.4.2 (f) (1) shall report in duplicate to the Agency, any changes in the information furnished by him in the "Certificate - Medical Use of Radioactive Material Under General License," Agency Form GEN-2. The report shall be submitted within 30 days after the effective date of such change.

(5) Any person using radioactive material pursuant to the general license of C.4.2 (f) (1) is exempt from the requirements of A.1 - A.6 of these regulations with respect to the radioactive material covered by the general license.

(g) General License for Use of Radioactive Material for Certain in Vitro Clinical or Laboratory Testing.[8]

(1) A general license is hereby issued to any physician, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of C.4.2 (g) (2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units:

(i) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

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[8]The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

C.4.2 (g) (1) (ii)

(ii) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(iii) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(iv) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(v) Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(vi) Cobalt-57, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(vii) Selenium-75, in units not to exceed 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(viii) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for in vitro clinical use or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by C.4.2 (g) (1) until he has filed Agency Form GEN-3 "Certificate - In Vitro Testing with Radioactive Material Under General License," with the Agency and received from the Agency a validated copy of Agency Form GEN-3 with certification number assigned. The physician, clinical laboratory or hospital shall furnish on Agency Form GEN-3 the following information and such other information as may be required by that form;

(i) name and address of the physician, clinical laboratory or hospital;

C.4.2 (g) (2) (ii)

(ii) the location of use; and

(iii) a statement that the physician, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in C.4.2 (g) (1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by C.4.2 (g) (1) shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in C.4.2 (g) (1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries.

(ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(iii) The general licensee shall use the radioactive material only for the [illegible] authorized by C.4.2 (g) (1).

(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U. S. Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in C.4.2 (g) (1) (viii) as required by A.4.1 of these regulations.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to C.4.2 (g) (1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to C.5.5 (h) or in accordance with the provisions of a specific license issued by the U. S. Nuclear Regulatory Commission, any Agreement State or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under C.4.2 or its equivalent, and

C.4.2 (g) (4) (ii)

(ii) unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(a) This radioactive material shall be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U. S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

(b) This radioactive material shall be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

_____
Name of Manufacturer

(5) The physician, clinical laboratory or hospital possessing or using radioactive material under the general license of C.4.2 (g) (1) shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License," Agency Form GEN-3. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of C.4.2 (g) (1) is exempt from the requirements of A.1-A.6 of these regulations with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in C.4.2 (g) (1) (viii) shall comply with the provisions of A.4.1, A.5.2 and A.5.3 of these regulations.

C.4.2 (h)

(h) Ice Detection Devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U. S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in section 32.61 of 10 CFR part 32 of the regulations of the U. S. Nuclear Regulatory Commission.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in C.4.2 (h) (1),

(i) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U. S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of A.4.1 of these regulations;

(ii) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(iii) are exempt from the requirements of A.1-A.6 of these regulations except that such persons shall comply with the provisions of A.4.1, A.5.2 and A.5.3.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of A.7, C.5.7, C.5.14, C.5.15, and C.7.1 of these regulations.

C.4.3 Intrastate Transportation of Radioactive Material.

(a) A general license is hereby issued to any common or contract carrier to transport and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the U. S. Department of Transportation insofar as such regulations relate to the loading and storage of packages, placarding of the

transporting vehicle, and incident reporting.[9] Persons who transport and store radioactive material pursuant to the general license in this paragraph are exempt from the requirements of A.1-A.6 of these regulations.

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[9] Persons who transport radioactive material pursuant to the general license in C.4.3 (b) are exempt from the requirements of A.1-A.6 of these regulations to the extent that they transport radioactive material.

[9]Any notification of incidents referred to in these requirements shall be filed with, or made to, the Agency.

C.5 SPECIFIC LICENSES

C.5.1 Filing Application for Specific Licenses.

(a) Applications for specific licenses shall be filed in triplicate on a form prescribed by the Agency.

(b) The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) In his application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

(f) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

C.5.2 General Requirements for the Issuance of Specific Licenses. A license application will be approved if the Agency determines that:

(a) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in such a manner as to minimize danger to public health and safety or property;

(b) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(c) the issuance of the license will not be inimical to the health and safety of the public; and

(d) the applicant satisfies any applicable special requirements in C.5.3, C.5.4, or C.5.5

(e) Bonding Requirements (Reserved).

C.5.2 (f)

(f) Perpetual Care Requirements (Reserved).

C.5.3 Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material.

(a) Human Use of Radioactive Material in Institutions. In addition to the requirements set forth in C.5.2, a specific license for human use of radioactive material in institutions will be issued if:

(1) The applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of radioactive material within that institution. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assay of radioactive material and protection against radiation;

(2) the applicant possesses adequate facilities for the clinical care of patients;

(3) the physician designated on the application as the individual user has substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and

(4) if the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

(b) Specific Licenses to Individual Physicians for Human Use of Radioactive Material.

(1) An application by an individual physician or group of physicians for a specific license for human use of radioactive material will be approved if:

(i) the applicant satisfies the general requirements specified in C.5.2;

(ii) the application is for use in the applicant's practice in an office outside a medical institution;

(iii) the applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(iv) the applicant has extensive experience in the proposed use, the handling and administration of radionuclides, and where applicable, the clinical management of radioactive patients.

(2) The Agency will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:

C.5.3 (b) (2) (i)

(i) the use of radioactive material is limited to:

(a) the administration of radiopharmaceuticals for diagnostic or therapeutic purposes.

(b) the performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered,

(c) the performance of in vitro diagnostic studies, or

(d) the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation;

(ii) the physician brings the radioactive material with him and removes the radioactive material when he departs. (The institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient); and

(iii) the medical institution does not hold a radioactive material license under C.5.3 (a).

(c) Specific Licenses for Certain Groups of Medical Uses of Radioactive Material.

(1) Subject to the provisions of C.5.3 (c) (2), (3), and (4), an application for a specific license pursuant to C.5.3 (a) or (b) for any medical use or uses of radioactive material specified in one or more of Groups I to VI, inclusive, of Appendix C of this part will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:

(i) the applicant satisifes the requirements of C.5.3 (a), (b) and (d);

(ii) the applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups;

(iii) the applicant, or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material, have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;

(iv) the applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups; and

(v) the applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.

(2) Any licensee or registrant who is authorized to use radioactive material pursuant to one or more groups in C.5.3 (c) (1) and Appendix C of this part is subject to the following conditions:

(i) For groups I, II, IV, and V, no licensee or registrant shall receive, possess, or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to C.5.5 (j), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.

(ii) For Group III, no licensee or registrant shall receive, possess, or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material except:

(a) reagent kits not containing radioactive material that are approved by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State for use by persons licensed pursuant to C.5.3 (c) and Appendix C of this part or equivalent regulations; or

(b) generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to C.5.5 (k), a specific license issued by the U.S. Nuclear Regulatory Commission, pursuant to Section 32.73 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.

(iii) For Group VI, no licensee or registrant shall receive, possess, or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to C.5.5 (l), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.

(iv) For Group III, any licensee or registrant who uses generators or reagent kits shall elute the generator or process radioactive material with the reagent kit in accordance with instructions which are approved by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and are furnished by the manufacturer on the label attached to or in the leaflet or brochure which accompanies the generator or reagent kit.

(v) For Group VI any licensee who possesses and uses sources or devices containing radioactive material shall:

C.5.3 (c) (2) (v) (a)

(a) cause each source or device containing more than 100 microcuries of radioactive material with a half-life greater than thirty days, except iridium-192 seeds encased in nylon ribbon, to be tested for contamination and/or leakage at intervals not to exceed 6 months or at such other intervals as are approved by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and described by the manufacturer or the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within six months prior to the transfer;

(b) assure that the test required by C.5.3 (c) (2) (v) (a) shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample or in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency;

(c) if the test required by C.5.3 (c) (2) (v) (a) reveals the presence of 0.005 microcurie or more of removable contamination or in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours, immediately withdraw the source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with Agency regulations. A report shall be filed within 5 days of the test with the Agency, describing the equipment involved, the test results, and the corrective action taken;

(d) follow the radiation safety and handling instructions approved by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form;

(e) conduct a quarterly physical inventory to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory;

(f) assure that needles or standard medical applicator cells containing radium-226 or cobalt-60 as wire are not opened while in the licensee's possession unless specifically authorized by a license issued to him by the Agency; and

(g) assure that patients containing cobalt-60, cesium-137, iridium-192 and/or radium-226, implants shall remain hospitalized until the implants are removed.

(3) Any licensee who is licensed pursuant to C.5.3 (c) (1) for one or more of the medical use groups in Appendix C also is authorized to use radioactive material under the general license in C.4.2 (g) for the specified in vitro uses without filing Form GEN-3 as required by C.4.2 (g) (2); provided, that the licensee is subject to the other provisions of C.4.2 (g).

(4) Any licensee who is licensed pursuant to C.5.3 (c) (1) for one or more of the medical use groups in Appendix C also is authorized, subject to the provisions of C.5.3 (c) (4) and (5), to receive, possess, and use for calibration and reference standards:

(i) any radioactive material listed in Group I, Group II or Group III of Appendix C of this part with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries total;

(ii) any radioactive material listed in Group I, Group II, or Group III of Appendix C of this part with half-life greater than 100 days in amounts not to exceed 200 microcuries total;

(iii) technetium-99m in amounts not to exceed 30 millicuries; and

(iv) any radioactive material, in amounts not to exceed 3 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to C.5.5 (1), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.

(5) (i) Any licensee or registrant who possess sealed sources as calibration or reference sources pursuant to C.5.3 (c) (4) shall cause each sealed source containing radioactive material, other than hydrogen-3, with a half-life greater than 30 days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within 6 months prior to the transfer, the sealed sources should not be used until tested, provided, however, that no leak tests are required when:

(a) the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material, or

(b) the sealed source is stored and is not being used; such

sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within 6 months prior to the date of use or transfer.

(ii) The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency.

(iii) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Parts A and C of these regulations. A report shall be filed within 5 days of the test with the Agency describing the equipment involved, the test results, and the corrective action taken.

(6) Any licensee or registrant who possesses and uses calibration and reference sources pursuant to C.5.3 (c) (4) (iv) shall:

(i) follow the radiation safety and handling instructions approved by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form; and

(ii) conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.

(d) Human use of Sealed Sources. In addition to the requirements set forth in C.5.2, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user:

(1) has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training, and

(2) is a physician.

(e) Use of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in C.5.2, a specific license for use of sealed sources in industrial radiography will be issued if:

(1) the applicant will have an adequate program for training radiographers and radiographer's assistants and submits to the Agency a schedule or description of such program which specifies the:

(i) initial training,

(ii) periodic training,

(iii) on-the-job training,

(iv) means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with Agency regulations and licensing requirements, and the operating and emergency procedures of the applicant, and

(v) means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(2) the applicant has established and submits to the Agency satisfactory written operating and emergency procedures (described in E.2.11 of these regulations);

(3) the applicant will have an adequate internal inspection system,or other management control, to assure that license provisions, regulations, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants; the inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for two years.

(4) the applicant submits to the Agency a description of his overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

(5) the applicant who desires to conduct [illegible]m leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Agency a description of such procedures including:

(i) instrumentation to be used,

(ii) method of performing tests, e.g., points on equipment to be smeared and method of taking smear, and

(iii) pertinent experience of the person who will perform the test; and

C.5.3 (e) (6)

(6) the licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

C.5.4 Special Requirements for Specific Licenses of Broad Scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain regulations governing holders of such licenses.[11]

(a) The different types of broad licenses are set forth below:

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix D, for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix D, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(b) An application for a Type A specific license of broad scope will be approved if:

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[11] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

C.5.4 (b) (1)

(1) the applicant satisfies the general requirements specified in C.5.2;

(2) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(ii) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) the establishment of appropriate administrative procedures to assure:

(a) control of procurement and use of radioactive material;

(b) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(c) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with C.5.4 (b) (3) (iii) (b) prior to use of the radioactive material.

(c) An application for a Type B specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in C.5.2; and

(2) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

(ii) the establishment of appropriate administrative procedures to assure:

C.5.4 (c) (2) (ii) (a)

(a) Control of procurement and use of radioactive material,

(b) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(c) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with C.5.4 (c) (2) (ii) (b) prior to use of the radioactive material.

(d) An application for a Type C specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in C.5.2;

(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(i) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and

(ii) At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

(e) Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to C.5.4 shall not:

(i) Conduct tracer studies in the environment involving direct release of radioactive material;

(ii) Receive, acquire, own, possess, use or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

(iii) Conduct activities for which a specific license issued by the Agency under C.5.3 or C.5.5 is required; or

C.5.4 (e) (1) (iv)

(iv) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of C.5.4 (d).

C.5.5 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material.

(a) Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations.

(1) In addition to the requirements set forth in C.5.2, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under C.2.2 (a) (1) will be issued if:

(i) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

(ii) The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Appendix A, that reconcentration of the radioactive material in concentrations exceeding those in Appendix A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic,

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drug, or other commodity or product designed for ingestion or inhalation by, or application to a human being.

(2) Each person licensed under C.5.5 (a) shall file an annual report with the Agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to C.5.5 (a) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

(b) Licensing the Distribution of Radioactive Material in Exempt Quantities.[11]

(1) An application for a specific license to distribute NARM to persons exempted from these regulations pursuant to C.2.2 (b) will be approved if:

(i) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(ii) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(iii) The applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures.

(2) The license issued under C.5.5 (b) (1) is subject to the following conditions:

(i) No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

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[11] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(ii) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to C.2.2 (b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(iii) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(a) Identifies the radionuclide and the quantity of radioactivity, and

(b) Bears the words "Radioactive Material."

(iv) In addition to the labeling information required by C.5.5 (b) (2) (iii), the label affixed to the immediate container, or an accompanying brochure, shall:

(a) State that the contents are exempt from Licensing State requirements,

(b) Bear the words "Radioactive Material--Not for Human Use--Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not Be Combined," and

(c) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(3) Each person licensed under C.5.5 (b) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under C.2.2 (b) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to C.5.5 (b) during the reporting period, the report shall so indicate.

(c) Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under C.2.2 (c) (3) will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32.

(d) Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under C.4.2 (b).

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under C.4.2 (b) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

(i) the applicant satisfies the general requirements of C.5.2;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(a) the device can be safely operated by persons not having training in radiological protection;

(b) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calender quarter a dose in excess of 10% of the limits specified in the table in A.2.1 (a); and

(c) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rems
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200 rems
Other organs	50 rems

(iii) Each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

(a) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(b) the requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(c) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(1) The receipt, possession, use, and transfer of this device, Model _____[12], Serial No. _____[12], are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____
(Name of manufacturer or distributor)

(2) The receipt, possession, use, and transfer of this device, Model _____[12], Serial No. _____[12], are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____ _____
(Name of manufacturer or distributor)

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for

[12]The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

the test for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:

(i) primary containment (source capsule);

(ii) protection of primary containment;

(iii) method of sealing containment;

(iv) containment construction materials;

(v) form of contained radioactive material;

(vi) maximum temperature withstood during prototype tests;

(vii) maximum pressure withstood during prototype tests;

(viii) maximum quantity of contained radioactive material;

(ix) radiotoxicity of contained radioactive material; and

(x) operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under C.4.2 (b), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calender quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10% of the limits specified in the table in A.2.1 (a).

(4) Each person licensed under C.5.5 (d) to distribute devices to generally licensed persons shall:

(i) Furnish a copy of the general license contained in C.4.2 (b) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in C.4.2 (b).

(ii) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's or Licensing State's regulation equivalent to C.4.2 (b), or alternatively, furnish a copy of the general license contained in C.4.2 (b) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State or the Licensing State. If a copy of the general license in C.4.2 (b) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State under requirements substantially the same as those in C.4.2 (b).

(iii) Report to the Agency all transfers of such devices to persons for use under the general license in C.4.2 (b). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under C.4.2 (b) during the reporting period, the report shall so indicate. The report shall cover each calender quarter and shall be filed within 30 days thereafter.

(iv) Reports to Other Agencies.

(a) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31.

(b) Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to C.5.5 (d) for use under a general license in that State's regulations equivalent to C.4.2 (b).

(c) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include

identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

(d) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

(e) If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of the agency.

(v) Keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in C.4.2 (b), or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records should show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of C.5.5 (d) (4).

(e) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under C.4.2 (c) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirements specified in C.5.2 and

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, 32.101 of 10 CFR Part 32 or their equivalent.

(f) Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under C.4.2 (e). An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under C.4.2 (e) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirement of C.5.2, and

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.60, 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

(g) Manufacture and Distribution of Radioactive Material for Medical Use Under General License. In addition to requirements set forth in C.5.2, a specific license authorizing the distribution of radioactive material for use by physicians under the general license in C.5.2 (f) will be issued if:

(1) The applicant submits evidence that the radioactive material is to be manufactured, labeled, and packaged in accordance with a new drug application which the Commissioner of Food and Drugs, Food and Drug Administration, has approved, or in accordance with a license for a biologic product issued by the Secretary, Department of Health, Education, and Welfare; and

(2) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:

(i) This radioactive drug may be received, possessed, and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

(ii) This radioactive drug may be received, possessed, and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license or its equivalent of a Licensing State.

_____
Name of manufacturer

(h) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of C.4.2 (g) will be approved if:

(1) The applicant satisfies the general requirements specified in C.5.2.

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(i) Iodine-125 in units not exceeding 10 microcuries each.

(ii) Iodine-131 in units not exceeding 10 microcuries each.

(iii) Carbon-14 in units not exceeding 10 microcuries each.

(iv) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

(v) Iron-59 in units not exceeding 20 microcuries each.

(vi) Cobalt-57 in units not exceeding 10 microcuries each

(vii) Selenium-75 in units not exceeding 10 microcuries each.

(viii) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(3) Each prepackaged unit bears a durable, clearly visible label:

(i) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries of hydrogen-3 (tritium); 20 microcuries of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and

(ii) Displaying the radiation caution symbol described in A.3.3 (a) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(i) This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or

or animal . Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.

_____
Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in A.4.1 of these regulations.

(i) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under C.4.2 (b) will be approved subject to the following conditions:

(1) The applicant satisfies the general requirements of C.5.2, and

(2) The criteria of Sections 32.61, 32.62, 32.63, 32.103 of 10 CFR Part 32 are met.

(j) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to C.5.3 (c) for the uses listed in Group I, Group II, IV, or V of Appendix C of this part will be approved if:

(1) The applicant satisfies the general requirements specified in C.5.2 of this part;

(2) The applicant submits evidence that:

(i) the radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

(ii) the manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material

which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

(4) (i) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed pursuant to C.5.3 (c) and Appendix C Group I, Group II, Group IV, and Group V of Part C, as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

(ii) The labels, leaflets or brochures required by C.5.5 (j) (4) (i) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(k) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to C.5.3(c) for the uses listed in Group III of Appendix C of this part will be approved if:

(1) The applicant satisfies the general requirements specified in C.5.2;

(2) the applicant submits evidence that:

(i) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA, or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

(ii) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(i) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(ii) a statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the Agency pursuant to C.5.3 (c) and Appendix C Group III of Part C or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The labels, leaflets or brochures required by C.5.5 (k) are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

NOTE: Although the Agency does not regulate the manfuacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for separation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to C.5.3 (c) and Group III of Appendix C of this part may submit the pertinent information specified in C.5.5 (k).

(l) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to C.5.3 (c) for use as a calibration or reference source or for the uses listed in Group VI of Appendix C of this part will be approved if:

(1) The applicant satisifes the general requirements in C.5.2 of this part.

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) the radioactive material contained, its chemical and physical form, and amount,

(ii) details of design and construction of the source or device,

(iii) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) for devices containing radioactive material, the radiation profile of a prototype device,

(v) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) procedures and standards for calibrating sources and devices,

(vii) legend and methods for labeling sources and devices as to their radioactive content, and

(viii) instruction for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthly for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the (name of source or device) is licensed by the Agency for distribution to persons licensed pursuant to C.5.3 (c) and Appendix C Group VI of this part or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, provided, that such labeling for sources which do not require long term storage (e.g., gold-198 seeds) may be on a leaflet or brochure which accompanies the source.

(4) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(5) In determining the acceptable interval for test of leakage of radioactive material, the Agency will condiser information that includes, but is not limited to:

(i) primary containment (source capsule),

(ii) protection of primary containment,

(iii) method of sealing containment,

(iv) containment construction materials,

(v) form of contained radioactive material,

(vi) maximum temperature withstood during prototype tests,

(vii) maximum pressure withstood during prototype tests,

(viii) maximum quantity of contained radioactive material,

(xi) radiotoxicity of contained radioactive material, and

(x) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(m) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to C.4.1 (d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) the applicant satisfies the general requirements specified in C.5.2;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling and marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, and transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calender quarter a radiation dose in excess of 10 percent of the limits specified in A.2.1 (a); and

(iii) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under C.5.5 (m) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Agency may deny any application for a specific license under C.5.5 (m) if the end use of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to C.5.5 (m) (1) shall

(i) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) label or mark each unit to:

(a) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(b) state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State;

(iii) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium;"

(iv) (a) furnish a copy of the general license contained in C.4.1 (d) and a copy of Agency Form GEN-1 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in C.4.1 (d), or

(b) furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to C.4.1 (d) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in C.4.1 (d) and a copy of Agency Form GEN-1 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in C.4.1 (d);

(v) report to the Agency all transfers of industrial products or devices to persons for use under the general license in C.4.1 (d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under C.4.1 (d) during the reporting period, the report shall so indicate;

(vi) (a) report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40,

C.5.5 (m) (4) (vi) (b)

(b) report to the responsible State agency all transfers of devices manufactured and distributed pursuant to C.5.5 (m) for use under a general license in that State's regulations equivalent to C.4.1 (d),

(c) such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person,

(d) if no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission,

(e) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency; and

(vii) keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in C.4.1 (d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

C.5.6 Issuance of Specific Licenses.

(a) Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

C.5.6 (b) (3)

(3) prevent loss or theft of material subject to this par .

C.5.7 Specific Terms and Conditions of License.

(a) Each licensee issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(c) Each person licensed by the Agency pursuant to this part shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

C.5.8 Expiration of Licenses. Except as provided in C.5.9 (b), each specific license shall expire at the end of the d y, in the month and year stated therein.

C.5.9 Renewal of Licenses.

(a) Applications for renewal of specific licenses shall be filed in accordance with C.5.1.

(b) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an applica ion in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the applicatio has been finally determined by the Agency.

C.5.10 Amendment of Licenses at Request of Licensee. Applications for amendment of a license shall be filed in accordance with C.5.1 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

C.5.11 Agency Action on Applications to be Renew and Amend. In considering an application by a licensee to renew or amend his license, the Agency will apply the criteria set forth in C.5.2 and C.5.3, C.5.4, or C.5.5 as applicable.

C.5.12 Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on Effective Date of These Regulations. Any person who, on the effective date of these regulations, possess a general or specific license for source, by-product, or special nuclear material in quantities not sufficient to form a critical mass, issued by the U.S. Nuclear Regulatory Commission, shall be deemed to possess a like license issued under this part and the Act, such license to expire either 90 days after receipt from the Agency of a

notice of expiration of such license, or on the date or expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

C.5.13 Persons Possessing Naturally Occurring and Accelerator-Produced Radioactive Material on Effective Date of These Regulations. Any person who, on the effective date of these regulations, possesses NARM for which a specific license is required by the Act or this part shall be deemed to possess such a license issued under the Act and this part. Such license shall expire 90 days after the effective date of these regulations; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the Agency.

C.5.14 Transfer of Material.

(a) No licensee shall transfer radioactive material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of C.5.14 (c) and (d), any licensee may transfer radioactive material:

(1) to the Agency;[13]

(2) to the U.S. Department of Energy;

(3) to any person exempt from the regulations in this part to the extent permitted under such exemption;

(4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, any Agreement State or any Licensing State; or

(5) as otherwise authorized by the Agency in writing.

(c) Before transferring radioactive material to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

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[13] A licensee may transfer material to the Agency only after receiving prior approval from the Agency.

C.5.14 (d)

(d) The following methods for the verification required by C.5.14 (c) are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) the transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(3) for emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days;

(4) the transferor may obtain other sources of information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State or a Licensing State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) when none of the methods of verification described in C.5.14 (d) (1) to (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or a Licensing State that the transferee is licensed to receive the radioactive material.

(e) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of C.7.1.

C.5.15 Modification, Revocation, and Termination of Licenses.

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Agency.

(b) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the Agency.

C.5.15 (c)

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.

C.6 RECIPROCITY

C.6.1 Reciprocal Recognition of Licenses

(a) Licenses of By-Product, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to these regulations, any person who holds a specific license from the U. S. Nuclear Regulatory Commission or any Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

(i) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) the out-of-state licensee notifies the Agency in writing at least three (3) days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three (3) day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.6.1 (a) (1);

(iii) the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;

(iv) the out-of-state licensee supplies such other information as the Agency may request; and

(v) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.6.1 (a) (1) except by transfer to a person:

(a) specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material, or

(b) exempt from the requirements for a license for such material under C.2.2 (a).

(2) Notwithstanding the provisions of C.6.1(a) (1), any person who holds a specific license issued by the U. S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in C.4.2 (b) (1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:

(i) such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U. S. Nuclear Regulatory Commission or an Agreement State;

(iii) such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(iv) the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in C.4.2 (b).

(3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determing that such action is necessary in order to prevent undue hazard to public health and safety or property.

(b) Licenses of Naturally-Occurring and Accelerator-Produced Radioactive Material.

(1) Subject to these regulations, any person who holds a specific license from any Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

(i) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) the out-of-state licensee notifies the Agency in writing at least three (3) days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three (3) day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.6.1 (b) (1);

(iii) The out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;

(iv) the out-of-state licensee supplies such other information as the Agency may request; and

(v) the out-of-state license shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.6.1 (b) (1) except by transfer to a person;

(a) specifically licensed by the Agency or by another Licensing State to receive such material, or

(b) exempt from the requirements for a license for such material under C.2.2.

(2) Notwithstanding the provisions of C.6.1 (b) (1), any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in C.4.2 (b) (1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:

(i) such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each

such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State;

(iii) such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(iv) the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in C.4.2 (b).

(3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

C.7 TRANSPORTATION

C.7.1 Preparation of Radioactive Material for Transport

(a) No licensee shall deliver any radioactive material to a carrier[14] for transport, unless:

(1) The licensee complies with the applicable requirements of the regulations, appropriate to the mode of transport, of the U. S. Department of Transportation insofar as such regulations relate to the packaging of radioactive material, and to the monitoring, marking and labeling of those packages;

(2) The licensee has established procedures for opening and closing packages in which radioactive material is transported to provide safety and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and

(3) Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to or have been available to the consignee.

(b) C.7.1 (a) shall not apply to the transportation of licensed material, or to the delivery of licensed material to a carrier for transport, where such transportation is subject to the regulations of the U. S. Department of Transportation or the U. S. Postal Service.

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[14] For the purpose of this regulation, a licensee who transports his own licensed material as a private carrier is considered to have delivered such material to a carrier for transport.

C.8 USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

C.8.1 Scope. These provisions apply to all licensees who use sealed sources in the healing arts and are in addition to, and not in substitution for, other applicable provisions of these regulations.

C.8.2 Interstitial, Intracavitary and Superficial Applications.

(a) Accountability, Storage and Transit.

(1) Except as otherwise specifically authorized by the Agency each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources. A physical inventory shall be made at least every 6 months and a written record of the inventory maintained.

(2) When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to assure compliance with the provisions of A.2 of these regulations.

(b) Testing Sealed Sources for Leakage and Contamination.

(1) All sealed sources with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination prior to initial use and at intervals not to exceed 6 months, unless otherwise specified. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.

(2) Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours. Any test conducted pursuant to C.8.2 (b) (1) which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours, shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of part A of these regulations.

(3) Leak test results shall be recorded in units of microcuries and maintained for inspection by the Agency.

(c) Radiation Surveys.

(1) The maximum radiation level at a distance of 1 meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation. This radiation level shall be entered on the patient's chart and other signs as required under C.8.2 (d).

(2) The radiation levels in the patient's room and the surrounding area shall be determined, recorded, and maintained for inspection by the Agency.

C.8.2 (d)

(d) Signs and Records.

(1) In addition to the requirements of A.3.3 of these regulations, the bed, cubicle, or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instructions. The sign is not required provided the exception in A.3.4 of these regulations is met.

(2) The following information shall be included in the patient's chart:

(i) The radionuclide administered, number of sources, activity in millicuries and time and date of administration;

(ii) The exposure rate at 1 meter, the time the determination was made, and by whom;

(iii) The radiation symbol; and

(iv) The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under A.2.1 of these regulations.

C.8.3 Teletherapy.

(a) Equipment.

(1) The housing shall be so constructed that, at 1 meter from the source, the maximum exposure rate does not exceed 10 milliroentgens per hour when the beam control mechanism is in the "off" position. The average exposure rate measured at a representative number of points about the housing, each 1 meter from the source, shall not exceed 2 milliroentgens per hour.

(2) For teletherapy equipment installed after the effective date of these regulations, the leakage radiation measured at 1 meter from the source when the beam control mechanism is in the "on" position shall not exceed 0.1 percent of the useful beam exposure rate.

(3) Adjustable or removable beam-defining diaphragms shall allow transmission of not more than 5 percent of the useful beam.

(4) The beam control mechanism shall be of a positive design capable of acting in any orientation of the housing for which it is designed to be used. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure.

(5) The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.

(6) When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.

(7) There shall be at the housing and at the control panel a warning device that plainly indicates whether the beam is "on" or "off."

(8) The equipment shall be provided with a locking device to prevent unauthorized use.

(9) The control panel shall be provided with a timer that automatically terminates the exposure after a pre-set time.

(10) Provision shall be made to permit continuous observation of patients during irradiation.

(b) Operation. No individual shall be in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.

(c) Testing for Leakage and Contamination. Teletherapy sources shall be tested for leakage and contamination in accordance with the procedures described in C.8.2 (b). Tests of leakage may be made by wiping accessible surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.

PART C

APPENDIX A

EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Antimony (51)	Sb-122		$3X10^{-4}$
	Sb-124		$2X10^{-4}$
	Sb-125		$1X10^{-3}$
Argon (18)	Ar-37	$1X10^{-3}$	
	Ar-41	$4X10^{-7}$	
Arsenic (33)	As-73		$5X10^{-3}$
	As-74		$5X10^{-4}$
	As-76		$2X10^{-4}$
	As-77		$8X10^{-4}$
Barium (56)	Ba-131		$2X10^{-3}$
	Ba-140		$3X10^{-4}$
Beryllium (4)	Be-7		$2X10^{-2}$
Bismuth (83)	Bi		$4X10^{-4}$
Bromine (35)	Br-82	$4X10^{-7}$	$3x10^{-3}$
Cadmium (48)	Cd-109		$2X10^{-3}$
	Cd-115m		$3X10^{-4}$
	Cd-115		$3X10^{-4}$
Calcium (20)	Ca-45		$9X10^{-5}$
	Ca-47		$5X10^{-4}$
Carbon (6)	C-14	$1X10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce-141		$9X10^{-4}$
	Ce-143		$4X10^{-4}$
	Ce-144		$1X10^{-4}$
Cesium (55)	Cs-131		$2X10^{-2}$
	Cs-134m		$6X10^{-2}$
	Cs-134		$9X10^{-5}$
Chlorine (17)	Cl-38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr-51		$2X10^{-2}$
Cobalt (27)	Co-57		$5X10^{-3}$
	Co-58		$1X10^{-3}$
	Co-60		$5X10^{-4}$

1/ Values are given in Column I only for those materials normally used as gases.

2/ μCi/gm for solids

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Copper (29)	Cu-64		$3X10^{-3}$
Dysprosium (66)	Dy-165		$4X10^{-3}$
	Dy-166		$4X10^{-4}$
Erbium (68)	Er-169		$9X10^{-4}$
	Er-171		$1X10^{-3}$
Europium (63)	Eu-152 (Tr=9.2 h)		$6X10^{-4}$
	Eu-155		$2X10^{-3}$
Fluorine (9)	F-18	$2X10^{-6}$	$8X10^{-3}$
Gadolinium (64)	Gd-153		$2X10^{-3}$
	Gd-159		$8X10^{-4}$
Gallium (31)	Ga-72		$4X10^{-4}$
Germanium (32)	Ge-71		$2X10^{-2}$
Gold (79)	Au-196		$2X10^{-3}$
	Au-198		$5X10^{-4}$
	Au-199		$2X10^{-3}$
Hafnium (72)	Hf-181		$7X10^{-4}$
Hydrogen (1)	H-3	$5X10^{-6}$	$3X10^{-2}$
Indium (49)	In-113m		$1X10^{-2}$
	In-114m		$2X10^{-4}$
Iodine (53)	I-126	$3X10^{-9}$	$2X10^{-5}$
	I-131	$3X10^{-9}$	$2X10^{-5}$
	I-132	$8X10^{-8}$	$6X10^{-4}$
	I-133	$1X10^{-8}$	$7X10^{-5}$
	I-134	$2X10^{-7}$	$1X10^{-3}$
Iridium (77)	Ir-190		$2X10^{-3}$
	Ir-192		$4X10^{-4}$
	Ir-194		$3X10^{-4}$
Iron (26)	Fe-55		$8X10^{-3}$
	Fe-59		$6X10^{-4}$
Krypton (36)	Kr-85m	$1X10^{-6}$	
	Kr-85	$3X10^{-6}$	
Lanthanum (57)	La-140		$2X10^{-4}$
Lead (82)	Pb-203		$4X10^{-3}$
Lutetium (71)	Lu-177		$1X10^{-3}$

1/ Values are given in Column I only for those materials normally used as gases.

2/ µCi/gm for solids.

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Manganese (25)	Mn-52		$3X10^{-4}$
	Mn-54		$1X10^{-3}$
	Mn-56		$1X10^{-3}$
Mercury (80)	Hg-197m		$2X10^{-3}$
	Hg-197		$3X10^{-3}$
	Hg-203		$2X10^{-4}$
Molybdenum (42)	Mo-99		$2X10^{-3}$
Neodymium (60)	Nd-147		$6X10^{-4}$
	Nd-149		$3X10^{-3}$
Nickel (28)	Ni-65		$1X10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1X10^{-3}$
	Nb-97		$9X10^{-4}$
Osmium (76)	Os-185		$7X10^{-4}$
	Os-191m		$4X10^{-2}$
	Os-191		$2X10^{-3}$
	Os-193		$6X10^{-4}$
Palladium (46)	Pd-103		$3X10^{-3}$
	Pd-109		$9X10^{-4}$
Phosphorus (15)	P-32		$2X10^{-4}$
Platinum (78)	Pt-191		$1X10^{-3}$
	Pt-193m		$1X10^{-2}$
	Pt-197m		$1X10^{-2}$
	Pt-197		$1X10^{-3}$
Potassium (19)	K-42		$3X10^{-3}$
Praseodymium (59)	Pr-142		$3X10^{-4}$
	Pr-143		$5X10^{-4}$
Promethium (61)	Pm-147		$2X10^{-3}$
	Pm-149		$4X10^{-4}$
Rhenium (75)	Re-183		$6X10^{-3}$
	Re-186		$9X10^{-4}$
	Re-188		$6X10^{-4}$
Rhodium (45)	Rh-103m		$1X10^{-1}$
	Rh-105		$1X10^{-3}$

1/ Values are given in Column I only for those materials normally used as gases.

2/ µCi/gm for solids.

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Rubidium (37)	Rb-86		$7X10^{-4}$
Ruthenium (44)	Ru-97		$4X10^{-3}$
	Ru-103		$8X10^{-4}$
	Ru-105		$1X10^{-3}$
	Ru-106		$1X10^{-4}$
Samarium (62)	Sm-153		$8X10^{-4}$
Scandium (21)	Sc-46		$4X10^{-4}$
	Sc-47		$9X10^{-4}$
	Sc-48		$3X10^{-4}$
Selenium (34)	Se-75		$3X10^{-3}$
Silicon (14)	Si-31		$9X10^{-3}$
Silver (47)	Ag-105		$1X10^{-3}$
	Ag-110m		$3X10^{-4}$
	Ag-111		$4X10^{-4}$
Sodium (11)	Na-24		$2X10^{-3}$
Strontium (38)	Sr-85		$1X10^{-3}$
	Sr-89		$1X10^{-4}$
	Sr-91		$7X10^{-4}$
	Sr-92		$7X10^{-4}$
Sulfur (16)	S-35	$9X10^{-8}$	$6X10^{-4}$
Tantalum (73)	Ta-182		$4X10^{-4}$
Technetium (43)	Tc-96m		$1X10^{-1}$
	Tc-96		$1X10^{-3}$
Tellurium (52)	Te-125m		$2X10^{-3}$
	Te-127m		$6X10^{-4}$
	Te-127		$3X10^{-3}$
	Te-129m		$3X10^{-4}$
	Te-131m		$6X10^{-4}$
	Te-132		$3X10^{-4}$
Terbium (65)	Tb-160		$4X10^{-4}$
Thallium (81)	Tl-200		$4X10^{-3}$
	Tl-201		$3X10^{-3}$
	Tl-202		$1X10^{-3}$
	Tl-204		$1X10^{-3}$
Thulium (69)	Tm-170		$5X10^{-4}$
	Tm-171		$5X10^{-3}$

1/ Values are given in Column 1 only for those materials normally used as gases.

2/ µCi/gm for solids

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Tin (50)	Sn-113		$9X10^{-4}$
	Sn-125		$2X10^{-4}$
Tungsten (Wolfram) (74)	W-181		$4X10^{-3}$
	W-187		$7X10^{-4}$
Vanadium (23)	V-48		$3X10^{-4}$
Xenon (54)	Xe-131m	$4X10^{-6}$	
	Xe-133	$3X10^{-6}$	
	Xe-135	$1X10^{-6}$	
Ytterbium (70)	Yb-175		$1X10^{-3}$
Yttrium (39)	Y-90		$2X10^{-4}$
	Y-91		$3X10^{-2}$
	Y-91		$3X10^{-4}$
	Y-92		$6X10^{-4}$
	Y-93		$3X10^{-4}$
Zinc (30)	Zn-65		$1X10^{-3}$
	Zn-69m		$7X10^{-4}$
	Zn-69		$2X10^{-2}$
Zirconium (40)	Zr-95		$6X10^{-4}$
	Zr-97		$2X10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years.		$1X10^{-10}$	$1X10^{-6}$

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Appendix A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of Section C.2.2 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Appendix A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} = <1$$

1/ Values are given in Column I only for those materials used as gases.

2/ µCi/gm for solids.

PART C

APPENDIX B

EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-59 (Co 59)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1

Radioactive Material	Microcuries
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-87 (Ga 87)	100
Gallium-72 (Ga 72)	10
Germanium-71 (Ge 71)	100
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	10
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Md 149)	100
Nickel-59 (Ni 59)	100

Radioactive Material	Microcuries
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-45 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10

Radioactive Material	Microcuries
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10

Radioactive Material	Microcuries
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

For purposes of C.5.2 (e) where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine the amount of each isotope possessed and 1,000 times the amount in Appendix B for each of those isotopes when not in combination. The sum of the ratios of those quantities may not exceed one (i.e., unity).

Example:

$$\frac{\text{Amt. of Isotope A possessed}}{1000 \times \text{Appendix B quantity for Isotope A}} + \frac{\text{Amt. of Isotope B possessed}}{1000 \times \text{Appendix B quantity for Isotope B}} < 1$$

PART C

APPENDIX C

GROUPS OF MEDICAL USES OF RADIOACTIVE MATERIAL

GROUP I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion (does not include uses involving imaging and tumor localizations)

(1) Iodine-131 as sodium iodide ($Na^{131}I$) for measurement of thyroid uptake.

(2) Iodine-125 as sodium iodide ($Na^{125}I$) for measurement of thyroid uptake.

(3) Iodine-131 as iodinated human serum albumin (IHSA) for determination of blood and blood plasma volume and for studies of cardiovascular function and protein turnover.

(4) Iodine-125 as iodinated human serum albumin (IHSA) for determination of blood and blood plasma volume and for studies of cardiovascular function and protein turnover.

(5) Iodine-131 as labeled rose bengal for liver function studies.

(6) Iodine-125 as labeled rose bengal for liver function studies.

(7) Iodine-131 as labeled fats or fatty acids for fat absorption studies.

(8) Iodine-125 as labeled fats or fatty acids for fat absorption studies.

(9) Iodine-131 as labeled iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, sodium acetrizoate, or sodium iothalamate for kidney function studies.

(10) Iodine-125 as labeled iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, sodium acetrizoate, or sodium iothalamate for kidney function studies.

(11) Cobalt-57 as labeled cyanocobalamin for intestinal absorption studies.

(12) Cobalt-58 as labeled cyanocobalamin for intestinal absorption studies.

(13) Cobalt-60 as labeled cyanocobalamin for intestinal absorption studies.

(14) Chromium-51 as sodium chromate for determination of red blood cell volume and studies of red blood cell survival time and gastrointestinal blood loss.

(15) Chromium-51 as labeled human serum albumin for gastrointestinal protein loss studies.

(16) Iron-59 as chloride, citrate, or sulfate for iron turnover studies.

(17) Potassium-42 as chloride for potassium space determinations.

(18) Sodium-24 as chloride for sodium space determinations.

(19) Technetium-99m as pertechnetate for blood flow studies.

(20) Mercury as chlormerodrin for kidney function studies.

(21) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(22) Iodine-123 as sodium iodide (NaI) for measurement of thyroid uptake.

GROUP II. Use of prepared radiopharmaceuticals for diagnostic studies involving imaging and tumor localizations.

(1) Iodine-131 as sodium iodide for thyroid imaging.

(2) Iodine-125 as sodium iodide for thyroid imaging.

(3) Iodine-131 as iodinated human serum albumin (IHSA) for brain tumor localizations and cardiac imaging.

(4) Iodine-131 as macroaggregated iodinated human serum albumin for lung imaging.

(5) Iodine-131 as colloidal (macroaggregated) iodinated human serum albumin for liver imaging.

(6) Iodine-131 as labeled rose bengal for liver imaging.

(7) Iodine-131 as iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, or sodium acetrizoate for kidney imaging.

(8) Iodine-131 as sodium iodipamide for cardiac imaging.

(9) Iodine-131 as iodinated human serum albumin (IHSA) for placenta localization.

(10) Chromium-51 as sodium chromate for spleen imaging.

(11) Chromium-51 as labeled human serum albumin for placenta localization.

(12) Gold-198 in collodial form for liver imaging.

(13) Mercury-197 as labeled chlormerodrin for kidney and brain imaging.

(14) Mercury-203 as labeled chlormerodrin for brain imaging.

(15) Selenium-75 as labeled selenomethionine for pancreas imaging.

(16) Strontium-85 as nitrate or chloride for bone imaging in patients with suspected or diagnosed cancer.

(17) Technetium-99m as pertechnetate for brain imaging.

(18) Technetium-99m as pertechnetate for thyroid imaging.

(19) Technetium-99m as pertechnetate for salivary gland imaging.

(20) Technetium-99m as pertechnetate for blood pool imaging, including placenta localization.

(21) Technetium-99m as labeled sulfur colloid for liver, spleen, and bone marrow imaging.

(22) Technetium-99m as labeled macroaggregated human serum albumin for lung imaging.

(23) Any radioactive material in a radiopharmaceutical prepared from a reagent kit listed in Section (4) of Group III.

(24) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving imaging for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(25) Fluorine-18 in solution for bone imaging.

(26) Strontium-87m for bone imaging.

(27) Iodine-125 as fibrinogen for detection and monitoring of developing deep vein thrombosis.

(28) Ytterbium-169 as labeled diethylenetriaminepentaacetic acid (DPTA) for cisternography.

(29) Iodine-123 as sodium iodide (NaI) for thyroid imaging.

(30) Indium-113m as chloride for blood pool imaging, including placenta localization.

Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses.

(1) Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate for:

(i) bone imaging;

(ii) thyroid imaging;

(iii) salivary gland imaging;

(iv) blood pool imaging including placenta localization;

(v) blood flow studies; and

(vi) use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in sections (4) and (5) of this group.

(2) Yttrium-87/Strontium-87m generators for the elution of Strontium-87m for bone imaging.

(3) Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in (4) and (5) of this group.

(4) Reagent kits for preparation of technetium-99m labeled:

(i) sulfur colloid for liver, spleen and bone marrow imaging;

(ii) Iron-ascorbate-diethylenetriaminepentaacetic acid complex for kidney imaging;

(iii) diethylenetriaminepentaacetic acid (Sn) for kidney imaging and kidney function studies;

(iv) diethylenetriamine pentaacetic acid (Sn) for brain imaging;

(v) human serum albumin microspheres for lung imaging;

(vi) polyphosphates for bone imaging;

(vii) macroaggregated human serum albumin for lung imaging;

(viii) distannous etidronate complex for bone imaging;

(ix) stannous pyrophosphate for bone and cardiac imaging;

(x) human serum albumin for heart blood pool imaging;

(xi) medronate sodium for bone imaging; and

(xii) gluceptate sodium for brain and renal perfusion imaging.

(5) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which generator or reagent kit a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(6) Tin-113/Indium-113m generators for the elution of indium-113m as chloride for:

(i) Blood Pool imaging including placenta localization.

Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety.

(1) Iodine-131 as iodide for treatment of hyperthyroidism.

(2) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases.

(3) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.

(4) Any radioactive material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety.

(1) Gold-198 as colloid for intracavitary treatment of malignant effusions.

(2) Iodine-131 as iodide for treatment of thyroid carcinoma.

(3) Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

Group VI. Use of sources and devices containing radioactive material for certain medical uses.

(1) Americium-241 as a sealed source in a device for bone mineral analysis.

(2) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.

(3) Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.

(4) Gold-198 as seeds for interstitial treatment of cancer.

(5) Iodine-125 as a sealed source in a device for bone mineral analysis.

(6) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer.

(7) Strontium-90 sealed in an applicator for treatment of superficial eye conditions.

(8) Radon-222 as seeds for topical, interstitial, and intracavitary treatment of cancer.

(9) Radium-226 as a sealed source for topical, interstitial, and intracavitary treatment of cancer.

(10) Iodine-125 as seeds for interstitial treatment of cancer.

PART C

APPENDIX D

Limits for Broad Licenses (C.5.4)

Radioactive Material	Col. I curies	Col. II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-75	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1

Radioactive Material	Col. I curies	Col. II curies
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1

Radioactive Material	Col. I curies	Col. II curies
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-166	10	0.1
Rhenium-168	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.
Strontium-85	1	0.01

Radioactive Material	Col. I curies	Col. II curies
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01

Radioactive Material	Col. I curies	Col. II curies
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above	0.1	0.001

RHODE ISLAND RULES AND REGULATIONS

FOR THE

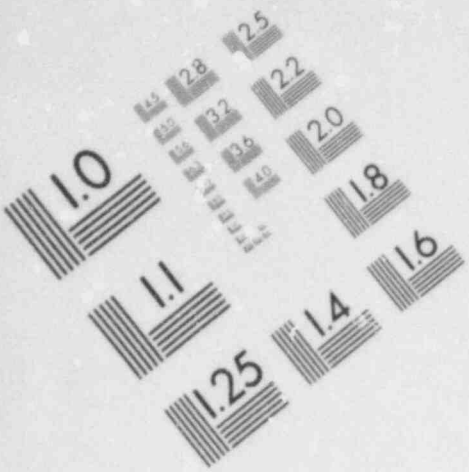
CONTROL OF RADIATION

PART D

RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

POOR ORIGINAL

Adopted 2 June 1978



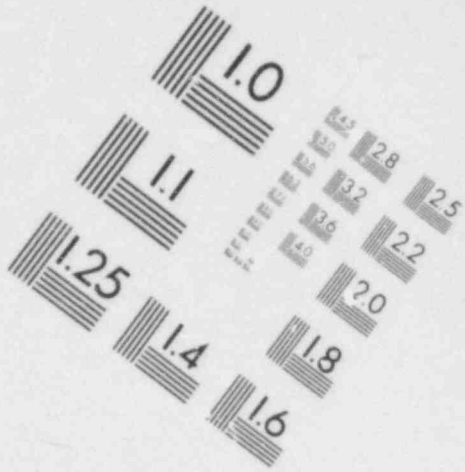
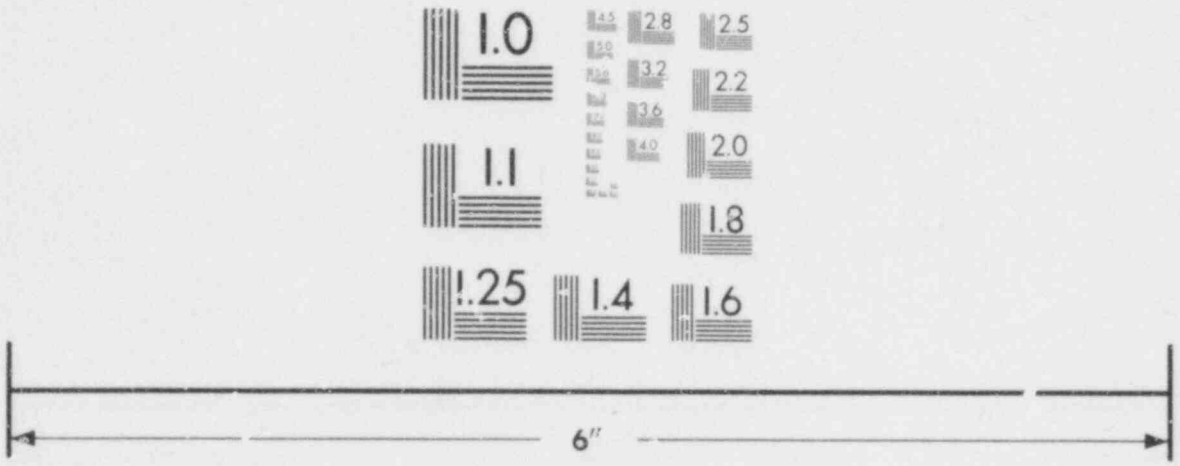
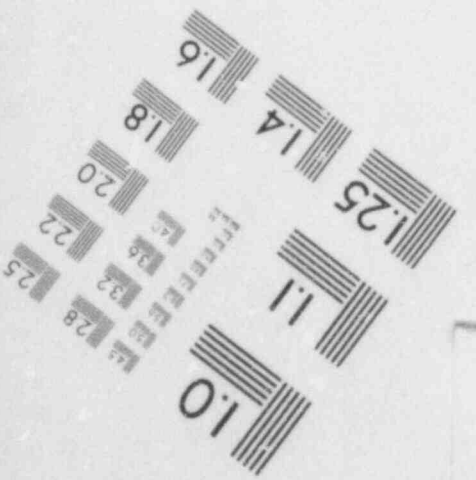
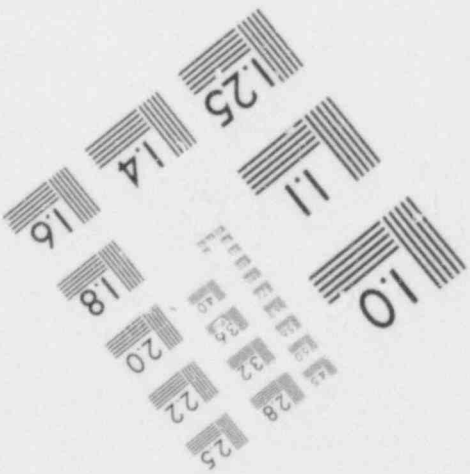
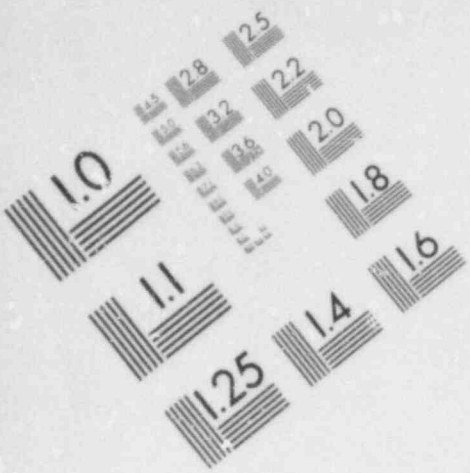


IMAGE EVALUATION TEST TARGET (MT-3)









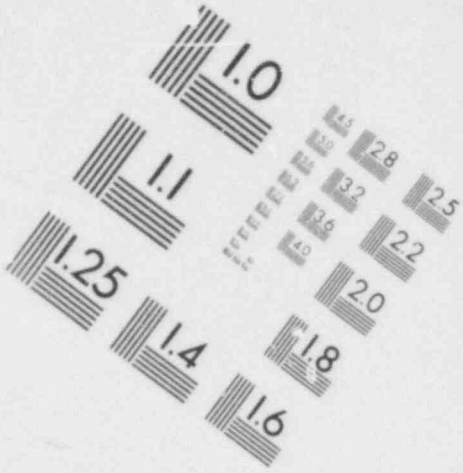
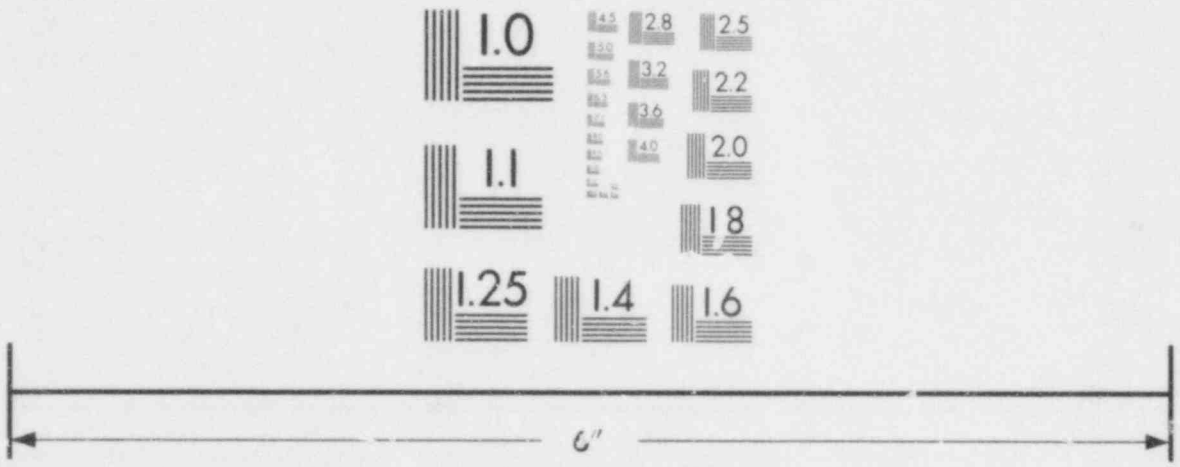
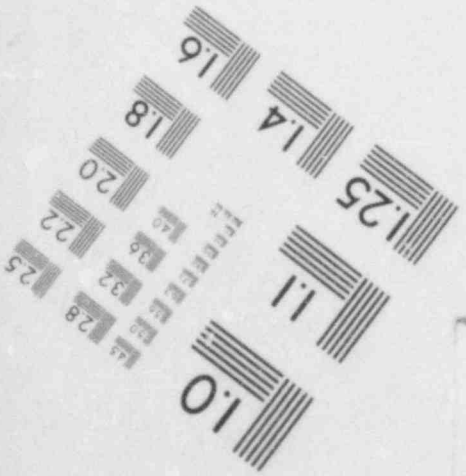
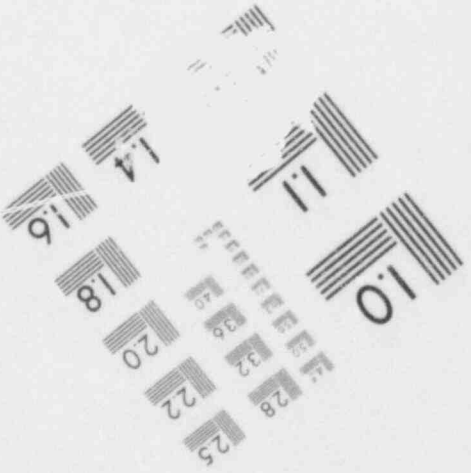
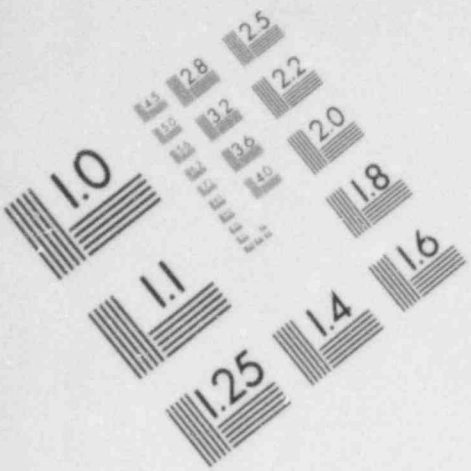


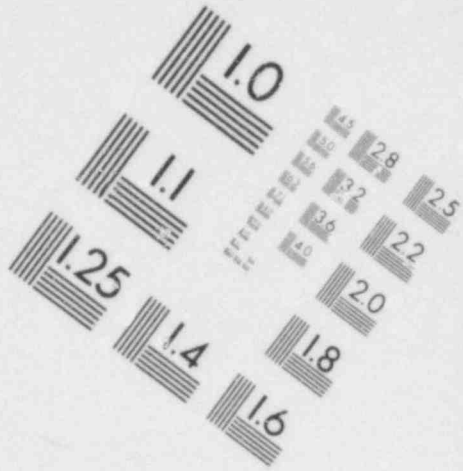
IMAGE EVALUATION TEST TARGET (MT-3)











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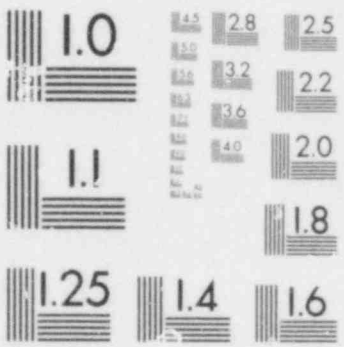

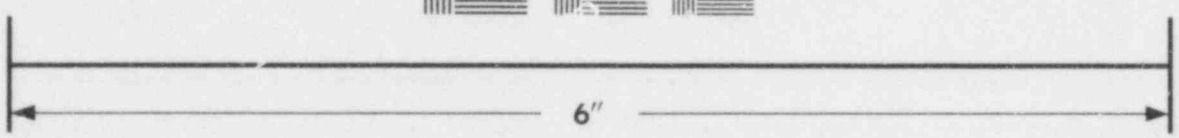

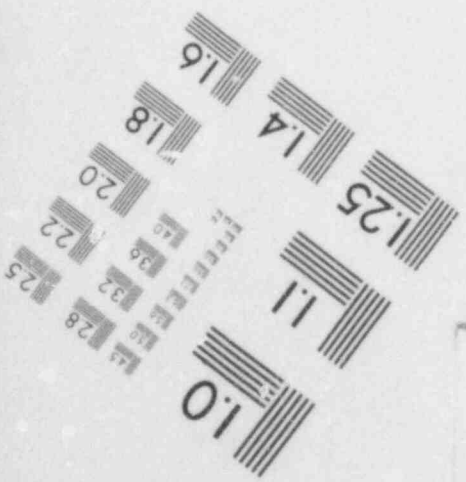

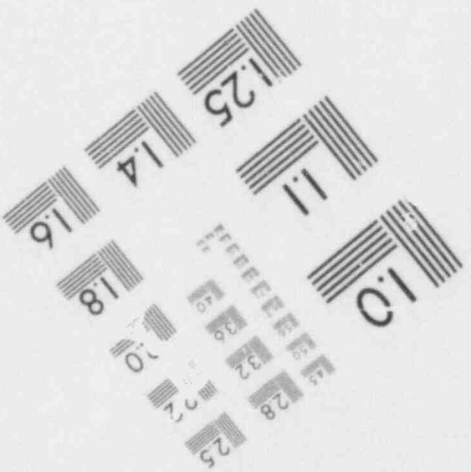

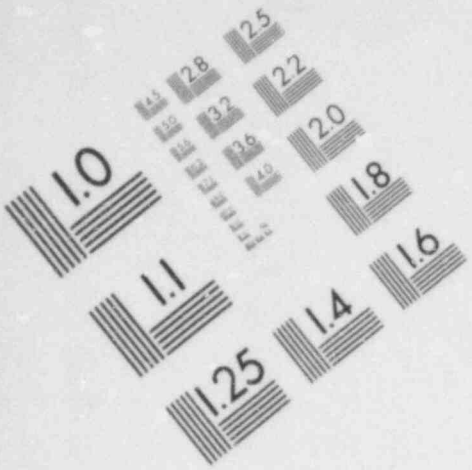

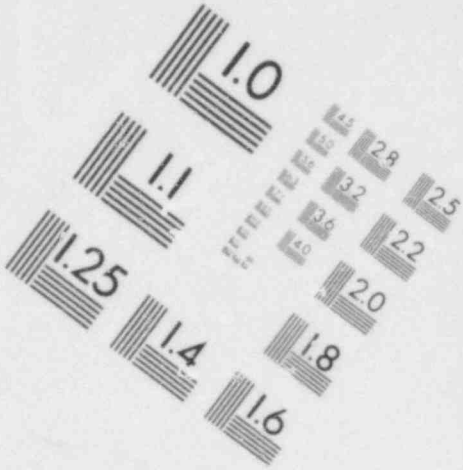

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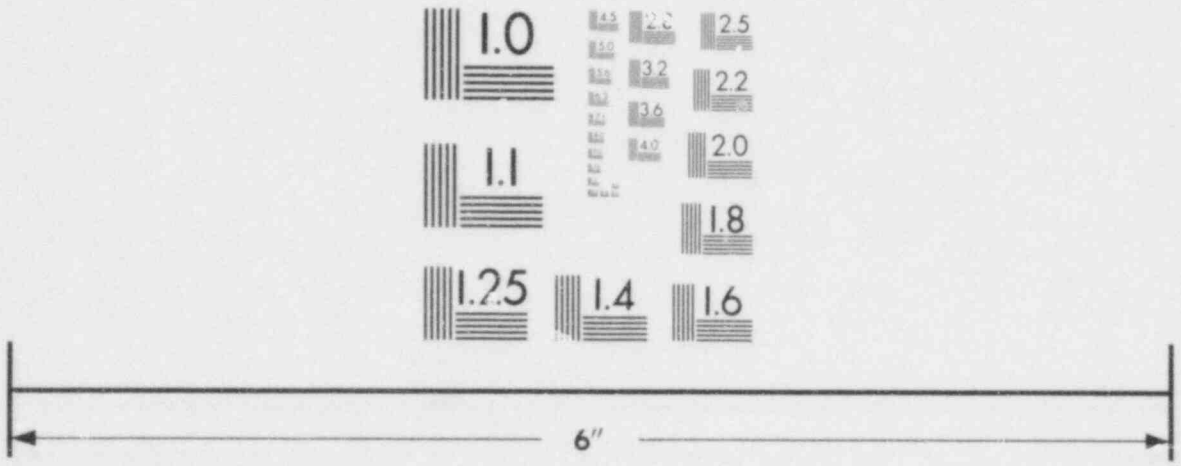

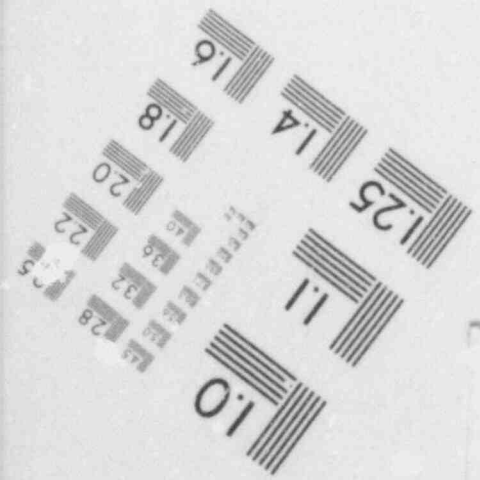

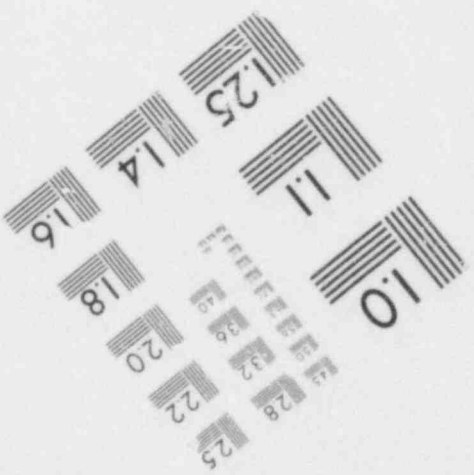

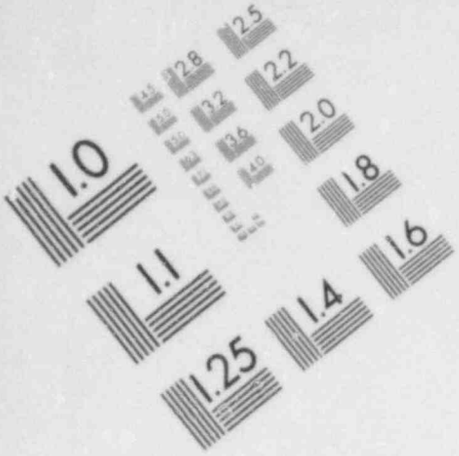

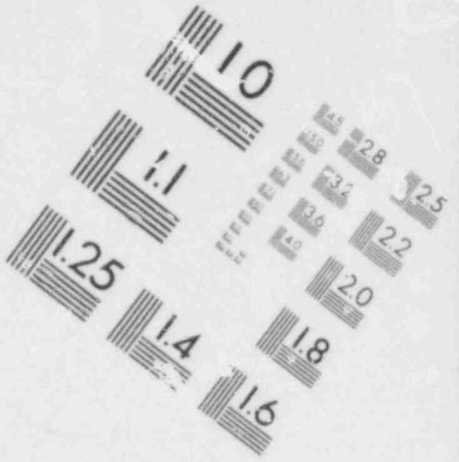

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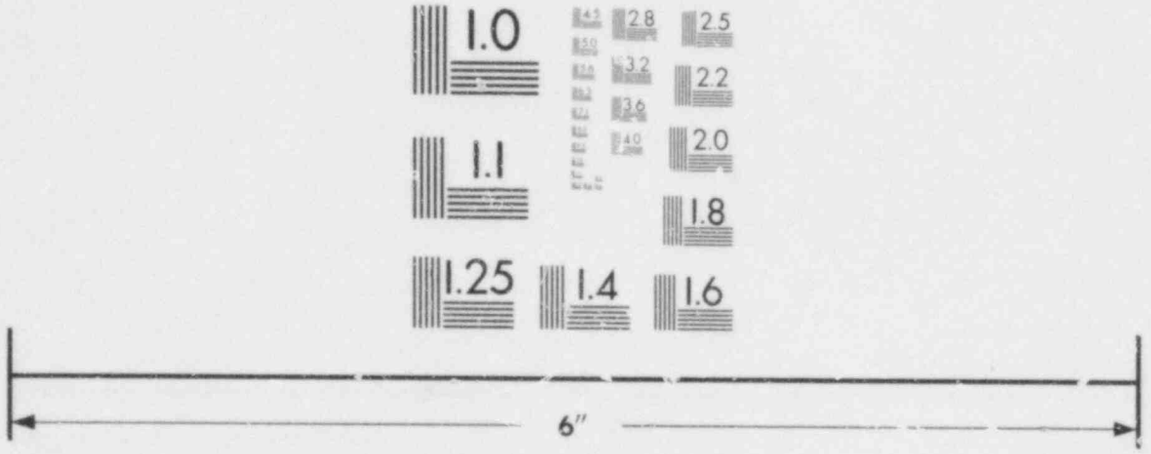

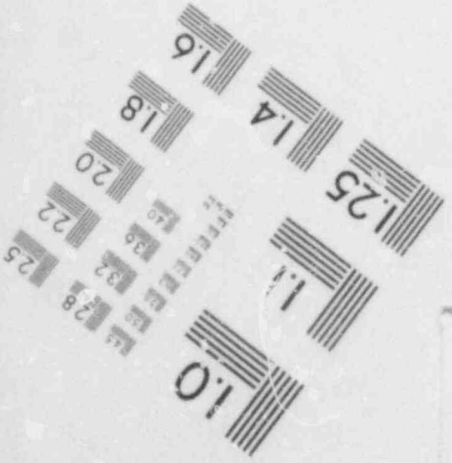

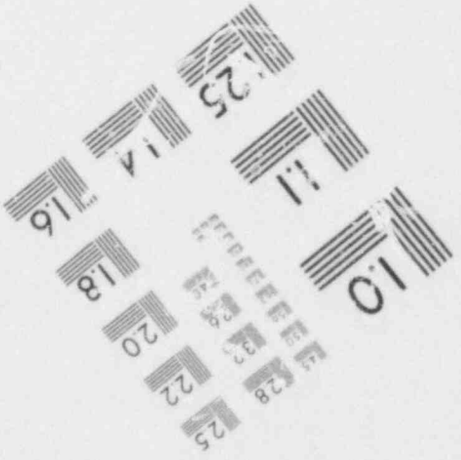

PART D

RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

D.1 Purpose and Scope.

D.1.1 This part establishes procedures for the registration and the use of particle accelerators.

D.1.2 In addition to the requirements of this part, all registrants are subject to the requirements of parts A and B. Registrants engaged in industrial radiographic operations are subject to the requirements of part E and registrants engaged in the healing arts are subject to the requirements of part F of these regulations. Registrants engaged in the production of radioactive material are subject to the requirements of part C.

D.2 REGISTRATION PROCEDURE

D.2.1 Registration Requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to these regulations or as otherwise provided for in these regulations. The general procedures for registration of particle accelerator facilities are included in part B of these regulations.

D.2.2 General Requirements for the Issuance of a Registration for Particle Accelerators.

In addition to the requirements of part B, a registration application for use of a particle accelerator will be approved only if the Agency determines that:

(a) The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this part and part A of these regulations in such a manner as to minimize danger to public health and safety or property;

(b) The applicant's proposed equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

(c) The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in section D.2.3 of this regulation;

(d) The applicant has appointed a radiation safety officer;

(e) The applicant and/or his staff has substantial experience in the use of particle accelerators for the intended uses;

(f) The applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the Agency; and

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D.2.2 (g)

(g) The applicant has an adequate training program for particle accelerator operators.

D.2.3 Human Use of Particle Accelerators. In addition to the requirements set forth in part B, a registration for use of a particle accelerator in the healing arts will be issued only if:

(a) Whenever deemed necessary by the Agency, the applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation;

(b) The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

(c) The individual designated on the application as the user must be a physician.

D.3 RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

D.3.1 General Provisions.

(a) This subpart establishes radiation safety requirements for the use of particle accelerators. The provisions of this subpart are in addition to, and not in substitution for, other applicable provisions of the regulations.

(b) The registrant shall be responsible for assuring that all requirements of this part are met.

D.3.2 Limitations.

(a) No registrant shall permit any person to act as a particle accelerator operator until such person:

(1) Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) Has received copies of and instruction in this part and the applicable requirements of part A, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in his assignment.

(b) Either the radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to protect health and minimize danger to public health and safety or property.

D.3.3 Shielding and Safety Design Requirements.

(a) A qualified expert, registered with the Agency, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

(b) Each particle accelerator installation shall be provided with such primary and/or secondary barriers as are necessary to assure compliance with sections A.2.1 and A.2.5.

D.3.4 Particle Accelerator Controls and Interlock Systems.

(a) Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

(b) All entrances into a target room or other high radiation area shall be provided with interlocks that shut down the machine under conditions of barrier penetration.

(c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped, and lastly at the main control console.

(d) Each safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.

(e) All safety interlocks shall be fail safe, i.e., designed so that any defect or component failure in the interlock system prevents operation of the accelerator.

(f) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

D.3.5 Warning Devices.

(a) All locations designated as high radiation areas, and entrances to such locations shall be equipped with easily observable flashing or rotating warning lights that operate when, and only when, radiation is being produced.

(b) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas and all radiation areas.

(c) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with section A.3.3.

D.3.6 Operating Procedures.

(a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

(c) All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed three months. Results of such tests shall be maintained for inspection at the accelerator facility.

(d) Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and maintained for inspection by the Agency and available to the operator at each accelerator facility.

(e) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(1) Authorized by the radiation safety committee and/or radiation safety officer;

(2) Recorded in a permanent log and a notice posted at the accelerator control console; and

(3) Terminated as soon as possible.

(f) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

D.3.7 Radiation Monitoring Requirements.

(a) There shall be available at each particle accelerator facility, appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. Such equipment shall be tested regularly and prior to use, and calibrated at intervals not to exceed one year, and after each servicing and repair which could affect the calibration.

(b) A radiation protection survey shall be performed and documented by a qualified expert registered with the Agency when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

(c) Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and interlock systems and capable of providing a remote and local readout with visual and/or audible alarms at both the control panel and at entrance to high radiation areas, and other appropriate locations, so that people entering or present become aware of the existence of the hazard.

(d) All area monitors shall be calibrated quarterly.

D.3.7 (e)

(e) Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.

(f) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.

(g) All area surveys shall be made in accordance with the written procedures established by a qualified expert, or the radiation safety officer of the particle accelerator facility.

(h) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility.

D.3.8 Ventilation Systems.

(a) Adequate ventilation shall be provided in areas where airborne radioactivity may be produced.

(b) A registrant, as required by section A.2.6, shall [illegible]nt, release or otherwise discharge airborne radioactive material to an uncontrolled area which exceed the limits specified in part A, Appendix A - Table II, except as authorized pursuant to section A.4.2 or paragraph A.2.6 (b). For purposes of this paragraph, concentrations may be averaged over a period not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to uncontrolled areas, as far below these limits as practicable.

RHODE ISLAND RULES AND REGULATIONS

FOR THE

CONTROL OF RADIATION

PART E

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS AND ANALYTICAL X-RAY EQUIPMENT

Adopted 2 June 1978

PART E

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS AND ANALYTICAL X-RAY EQUIPMENT

E.1 Purpose. The regulations in this part establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography, and provides special requirements for analytical and research and development x-ray equipment. The requirements of this part are in addition to and not in substitution for the other requirements of these regulations.

E.2 INDUSTRIAL RADIOGRAPHY

E.2.1 Scope. The regulations in this subpart apply to all licensees or registrants who use sources of radiation for industrial radiography; provided, however, that nothing in this subpart shall apply to the use of sources of radiation in the healing arts.

EQUIPMENT CONTROL

E.2.2 Limits on Levels of Radiation for Radiographic Exposure Devices and Storage Containers. Radiographic exposure devices measuring less than four (4) inches from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens per hour at six (6) inches from any exterior surface of the device. Radiographic exposure devices measuring a minimum of four (4) inches from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, and ten (10) milliroentgens per hour at one meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.

E.2.3 Locking of Sources of Radiation.

(a) Each source of radiation shall be provided with a lock or outer-locked container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer's assistant, or as may be otherwise authorized pursuant to section E.2.13. Each storage container likewise shall be provided with a lock and kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.

(b) Radiographic exposure devices and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position.

E.2.4 Storage Precautions. Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

F.2.5 Radiation Survey Instruments.

(a) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this subpart and A.3.1 of these regulations. Instrumentation required by this paragraph shall have a range such that 2 milliroentgens per hour through 1 roentgen per hour can be measured.

(b) Each radiation survey instrument shall be calibrated:

(1) Against appropriate energy at intervals not to exceed 3 months and after each instrument servicing;

(2) Such that accuracy within 20 percent traceable to a national standard can be demonstrated; and

(3) At two or more widely separated points, other than zero, on each scale.

(c) Records of these calibrations shall be maintained for two years after the calibration date for inspection by the Agency.

E.2.6 Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State.

(b) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 month period prior to the transfer, the sealed source shall not be put into use until tested.

(c) The leak test shall be capable of detecting the presence of 0.005 microcurie of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to part C. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency for 6 months after the next required leak test is performed or until the sealed source is transferred or disposed of.

(d) Any test conducted pursuant to paragraphs (b) and (c) of this section which reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with regulations of the Agency. Within 5 days after obtaining results of the test, the licensee shall file a report with the Agency describing the equipment involved, the test results, and the corrective action taken.

E.2.6 (e)

(e) A sealed source which is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least one (1) inch square bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger - Radioactive Material - Do Not Handle-Notify Civil Authorities if Found."

E.2.7 Quarterly Inventory. Each licensee shall conduct a quarterly physical inventory to account for all sealed sources received or possessed by him. The records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, the location of sealed sources, and the date of the inventory.

E.2.8 Utilization Logs. Each licensee or registrant shall maintain current logs, which shall be kept available for inspection by the Agency for two years from the date of the recorded event, showing for each source of radiation the following information:

(a) A description (or make and model number) of each source of radiation or storage container in which the sealed source is located;

(b) The identity of the radiographer to whom assigned; and

(c) Locations where used and dates of use.

E.2.9 Inspection and Maintenance of Radiographic Exposure Devices, Storage Containers, and High Radiation Area Control Devices or Alarm Systems.

(a) Each licensee shall conduct a program of at least quarterly inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer's specifications. Records of inspection and maintenance shall be maintained for inspection by the Agency until it authorizes their disposal. If any inspection reveals damage to components critical to radiation safety, the device shall be removed from service until repairs have been made.

(b) For any high radiation area equiped with a control device or alarm system as described in A.3.3 (c) (2) of these regulations, the control device or alarm system shall be tested for proper operation at the beginning of each period of use. Records of such tests shall be maintained for inspection by the Agency until it authorizes their disposal.

E.2.10 Limitations.

(a) No licensee or registrant shall permit any individual to act as a radiographer until such individual:

(1) Has been instructed in the subjects outlined in Appendix A of this part and shall have demonstrated understanding thereof;

(2) Has received copies of and instruction in the regulations contained in this subpart and the applicable sections of part A, appropriate license(s) or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) Has demonstrated competence to use the source of radiation, radiographic exposure device, related handling tools, and radiation survey instruments which will be employed in his assignment.

(b) No licensee or registrant shall permit any individual to act as a radiographer's assistant until such individual:

(1) Has received copies of and instruction in the licensee's or registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(2) Has demonstrated competence to use under the personal supervision of the radiographer the sources of radiation, radiographic exposure device, related handling tools, and radiation survey instruments which will be employed in his assignment.

(c) Each licensee or registrant shall maintain, for inspection by the Agency until it authorizes their disposal, records of instruction and testing which demonstrate that the requirements of E.2.10 (a) and (b) have been met.

E.2.11 Operating and Emergency Procedures. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(a) The handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in subpart A.2 Standards for Protection Against Radiation;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to radiographic areas;

(d) Methods and occasions for locking and securing sources of radiation;

(e) Personnel monitoring and the use of personnel monitoring equipment;

(f) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation:

(g) Minimizing exposure of individuals in the event of an accident;

(h) The procedure for notifying proper personnel in the event of an accident;

(i) Maintenance of records; and

(j) The inspection and maintenance of radiographic exposure devices and storage containers, and radiation machines.

E.2.12 Personnel Monitoring Control.

(a) No licensee or registrant shall permit any individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each such individual wears a direct reading pocket dosimeter and either a film badge or a thermoluminescent dosimeter. Pocket dosimeters shall have a range from zero to at least 200 milliroentgens and shall be recharged daily or at the start of each shift. Each film badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.

(b) Pocket dosimeters shall be read and exposures recorded daily. An individual's film badge or thermoluminescent dosimeter shall be immediately processed if his pocket dosimeter is discharged beyond its range. Reports received from the film badge or thermoluminescent dosimeter processor and records of pocket dosimeter readings shall be maintained for inspection by the Agency until it authorizes their disposal.

Precautionary Procedures in Radiographic Operations

E.2.13 Security. During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in part A, except:

(a) Where the high radiation area is equipped with a control device or alarm system as described in subparagraph A.3.3 (c) (2), or

(b) Where the high radiation area is locked to protect against unauthorized or accidental entry.

E.2.14 Posting. Notwithstanding any provisions in paragraph A.3.4 (c), areas in which radiography is being performed shall be conspicuously posted as required by A.3.3 (b) and (c) (1).

E.2.15 Radiation Surveys and Survey Records.

(a) No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation as described in section E.2.5 is available and used at each site where radiographic exposures are made.

(b) A physical radiation survey shall be made after each radiographic exposure utilizing radiographic exposure devices or sealed sources of radioactive material to determine that the sealed source has been returned to its shielded position.

(c) A physical radiation survey shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device or storage container as specified in section E.2.3.

E.2.15 (d)

(d) Records shall be kept of the surveys required by E.2.15 (c). Such records shall be maintained for inspection by the Agency for 2 years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the Agency authorizes their disposition.

E.2.16 Special Requirements and Exemptions for Enclosed Radiography.

(a) Systems for enclosed radiography designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this part and A.2.5 of these regulations. If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this part and 21 CFR 1020.40.

(2) Be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements as specified in E.2.16 (a) (1). Records of these evaluations shall be maintained for inspection by the Agency for a period of two years after the evaluation.

(b) Cabinet x-ray systems designed to exclude individuals are exempt from the requirements of this part except that:

(1) Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter and reports of the results must be maintained for inspection by the Agency.

(2) No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of instructions in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this sub-paragraph shall be maintained for inspection by the Agency until disposition is authorized by the Agency.

(3) Tests for proper operation of high radiation area control devices, or alarm systems, where applicable, must be conducted and recorded in accordance with E.2.9 (b).

(4) The registrant shall perform an evaluation, at intervals not to exceed one year, to determine conformance with A.2.5 of these regulations.

(c) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Agency pursuant to A.1.4 (a) of these regulations.

E.2.17 Records Required at Temporary Job Sites. Each licensee or registrant conducting industrial radiography at a temporary site shall have the following records available for inspection by the Agency:

(a) Appropriate license or certificate of registration.

(b) Operating and emergency procedures.

E.2.17 (c)

(c) Applicable regulations.

(d) Survey records required pursuant to E.2.15 for the period of operation at the site.

(e) Daily pocket dosimeter records for the period of operation at the site.

(f) The latest instrument calibration and leak test record for specific devices in use at the site.

E.3 ANALYTICAL AND RESEARCH AND DEVELOPMENT X-RAY EQUIPMENT

E.3.1 Equipment Requirements.

(a) Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant may apply to the Agency for an exemption from the requirement of a safety device. Such application shall include:

(1) A description of the various safety devices that have been evaluated,

(2) The reason each of these devices cannot be used, and

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) Warning Devices. Open-beam configurations shall be provided with a readily discernible indication of:

(1) X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(2) Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

Warning devices shall be labeled so that their purpose is easily identified. Warning devices shall have fail-safe characteristics.

(c) Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(d) Labeling. All analytical and research and development x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray source housing; and

E.3.1 (d) (2)

(2) "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or

(3) "CAUTION - RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing if the radiation source is a radionuclide.

(e) Shutters. On open-beam configurations each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(f) Warning Lights. An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located:

(1) Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or

(2) In the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.

Warning lights shall have fail-safe characteristics.

(g) Radiation Source Housing. Each x-ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 mrem in one hour at any specified tube rating.

(h) Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem in one hour.

E.3.2 Area Requirements.

(a) Radiation Levels. The local components of analytical and research and development x-ray systems shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in section A.2.5 of these regulations. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

(b) Surveys. Radiation surveys, as required by A.3.1, of all analytical and research and development x-ray systems sufficient to show compliance with paragraph E.3.2 (a) shall be performed:

(1) Upon installation of the equipment;

(2) Following any change in the initial arrangement, number, or type of local components in the system;

(3) Following any maintenance requiring the disassembly or removal of a local component in the system;

E.3.2 (b) (4)

(4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed; and

(5) Any time a visual inspection of the local components in the system reveals an abnormal condition.

(6) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the Radiation Protection Guides (radiation dose limits).

Radiation survey measurements shall not be required if a registrant can demonstrate compliance to the satisfaction of the Agency with E.3.2 (a) in some other manner.

(c) Posting. Each area or room containing analytical or research and development x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT," or words having a similar intent.

E.3.3 Operating Requirements.

(a) Procedures. Normal operating procedures shall be written and available to all analytical and research and development workers. No person shall be permitted to operate analytical or research and development x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the radiation safety officer.

(b) Bypassing. No person shall bypass a safety device unless such person has obtained the approval of the radiation safety officer. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

E.3.4 Personnel Requirements.

(a) Instruction. No person shall be permitted to operate or maintain analytical or research and development x-ray equipment unless such person has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with the use of the equipment;

(2) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(3) Proper operating procedures for the equipment;

(4) Symptoms of an acute localized exposure; and

(5) Proper procedures for reporting an actual or suspected exposure.

E.3.4 (b)

(b) Personnel Monitoring. Finger or wrist dosimetric devices shall be provided to and shall be used by:

(1) Analytical and research and development x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

(2) Personnel maintaining analytical or research and development x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical or research and development x-ray system is disassembled or removed.

Reported dose values shall not be used for the purpose of determining compliance with section A.2.1 of these regulations unless evaluated by a qualified expert.

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APPENDIX A

SUBJECTS TO BE COVERED DURING THE INSTRUCTION OF RADIOGRAPHERS

I. Fundamentals of Radiation Safety

A. Characteristics of gamma and x radiation
B. Units of radiation dose (mrem) and quantity of radioactivity (curie)
C. Hazards of excessive exposure to radiation
D. Levels of radiation from sources of radiation
E. Methods of controlling radiation dose

1. Working time
2. Working distances
3. Shielding

II. Radiation Detection Instrumentation to be Used

A. Use of radiation survey instruments

1. Operation
2. Calibration
3. Limitations

B. Survey techniques
C. Use of personnel monitoring equipment

1. Film badges
2. Pocket dosimeters
3. Thermoluminescent dosimeters

III. Radiographic Equipment to be Used

A. Remote handling equipment
B. Radiographic exposure devices and sealed sources
C. Storage containers
D. Operation and control of x-ray equipment

IV. The Requirements of Pertinent Federal and State Regulations

V. The Licensee's or Registrant's Written Operating and Emergency Procedures

RHODE ISLAND RULES AND REGULATIONS

FOR THE

CONTROL OF RADIATION

PART F

X-RAYS IN THE HEALING ARTS

Adopted 2 June 1978

PART F
X-RAYS IN THE HEALING ARTS

F.1 SCOPE

F.1.1 This part establishes requirements, for which a registrant is responsible, for use of x-ray equipment in the healing arts or veterinary medicine. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.

F.1.2 The use of x-ray equipment for the intentional exposure of individuals for diagnosis or treatment shall be by or under the supervision of a licensed practitioner of the healing arts.

F.1.3 The use of x-ray equipment in the practice of veterinary medicine shall be by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in veterinary medicine.

F.2 GENERAL REQUIREMENTS FOR ALL HEALING ARTS FACILITIES

F.2.1 Administrative Controls. The registrant shall be responsible for directing the operation of the x-ray systems which have been registered with the Agency. The registrant or the registrant's agent shall assure that the requirements of this part are met in the operation of the x-ray system(s).

F.2.2 An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes.

F.2.3 Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. As a minimum, such instruction shall consist of subjects outlined in Appendix B of this part.

F.2.4 A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel, which specifies for all examinations performed with that system the following information:

(a) Patient's anatomical size versus technique factors to be utilized;

(b) Type and size of the film or film-screen combination to be used;

(c) Type and focal distance of the grid to be used, if any;

(d) Source to image receptor distance to be used; and

(e) Type and location of placement of gonadal shielding to be used.

F.2.5 Written safety procedures and rules shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these rules.

F.2.6

F.2.6 Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(a) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

(b) Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

(c) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(d) Written safety procedures, as required by F.2.5, shall describe how the requirements of this section will be met when using mobile or portable x-ray systems.

F.2.7 Gonadal shielding of not less than 0.25 millimeter lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which the technique chart specifically indicates that this would interfere with the diagnostic procedure.

F.2.8 Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes, and exposure of an individual for the purpose of healing arts screening except as authorized by F.2.12.

F.2.9 When a patient or film must be provided with auxiliary support during a radiation exposure:

(a) Mechanical holding devices shall be used when the technique permits. The safety rules, required by F.2.5, shall list individual projections where holding devices cannot be utilized;

(b) Written safety procedures, as required by F.2.5, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(c) The human holder shall be protected as required by section F.2.6;

(d) No individual shall be used routinely to hold film or patients;

(e) Such holding shall be permitted only in very unusual and rare situations;

F.2.9 (f)

(f) In those cases where the patient must hold the film, except during dental examinations covered in subpart F.6, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

(g) A record shall be made of the examination and shall include the name of the human holder, date of the examination, number of exposures and technique factors utilized for the exposure(s).

F.2.10 Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include but is not limited to

(a) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(c) Portable or mobile equipment shall be used only for examinations where it is medically inadvisable or impractical to transfer the patient(s) to a stationary radiographic installation.

F.2.11 All individuals who are associated with the operation of an x-ray system are subject to the requirements of A.2.1 and A.2.2 of these regulations. In addition, when protective clothing or devices are worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized. When an apron is worn, the monitoring device shall be worn at the collar outside of the apron. The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by A.5.1 of these regulations. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

F.2.12 Healing Arts Screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix A of this part. If any information submitted to the Agency becomes invalid or out-dated, the Agency shall be immediately notified.

F.2.13 Information and Maintenance Record and Associated Information. The registrant shall maintain the following information in a separate file or package in chronological order for each x-ray system, for inspection by the Agency:

(a) Maximum rating of technique factors;

(b) Model and serial numbers of all certifiable components;

F.2.13 (c)

(c) Aluminum equivalent filtration of the useful beam, including any routine variation;

(d) Tube rating charts and cooling curves;

(e) Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after the effective date of this part with the names of persons who performed such services;

(f) A scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include the results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or the type and thickness of materials, or lead equivalency, of each protective barrier.

(g) A copy of all correspondence with this Agency regarding that x-ray system.

F.2.14 Each facility shall maintain an X-ray Patient Log containing the following information:

(a) Name, age, and sex of the patient.

(b) Date of x-ray examination.

(c) Examination(s) or treatment(s) given by routine or local title as denoted on the technique chart. In addition: for radiography, the number of exposures for each projection; for fluoroscopy, the cumulative fluoro on-time; for treatment utilizing x-rays of less than one Mev, the length of the exposure; for treatment utilizing x-rays of one Mev and above, an appropriate measure of the dose, e.g., dose monitor units.

(d) Any deviation from the standard procedure as specified on the technique chart, including all repeat exposures.

(e) When applicable, the x-ray system used.

(f) Name(s) of individuals who performed the examination.

(g) Name of the human holder, if used.

(h) Name of the licensed practitioner of the healing arts ordering the examination.

Patient log records shall be maintained for a minimum of five (5) years following the examination or treatment of adult patients. Records of examination or treatment of minors shall be maintained for a minimum of five (5) years beyond the age of majority.

F.3 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC X-RAY SYSTEMS

F.3.1 In addition to other requirements of this part, all diagnostic x-ray systems shall meet the requirements of this subpart.

F.3.2 Certified Systems and Components. Diagnostic x-ray systems, for use on humans, and their associated components certified pursuant to the Federal diagnostic x-ray standard shall be maintained in compliance with applicable requirements of such standard in Title 21, Code of Federal Regulations, Chapter I, Subchapter J.

F.3.3 Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

F.3.4 Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

F.3.5 Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 10 centimeters.

F.3.6 Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

F.3.7 Beam Quality.

(a) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

F.3.7 (a)

TABLE I

Design operating range (Kilovolts peak)	Measured potential (Kilovolts peak)	Half-value layer (Millimeters of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

The half-value layer requirement will be considered to have been met if it can be demonstrated that the aluminum equivalent of total filtration in the primary beam is not less than that shown in Table II.

TABLE II

Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	Total Filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 - 70	1.5 millimeters
Above 70	2.5 millimeters

(b) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

(c) For capacitor energy storage equipment, compliance with the half-value layer requirement shall be determined with the maximum quantity of charge per exposure.

F.3.7 (d)

(d) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

(e) For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by F.3.7 (a) is in the useful beam for the given kVp which has been selected.

F.3.8 Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

F.3.9 Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

F.3.10 Technique Indicators. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. This requirement may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

F.3.11 Structural Shielding. Structural shielding shall be provided whenever necessary to meet the requirements of A.2.1 and A.2.5, in addition to specific requirements contained in other parts of these regulations.

F.4 FLUOROSCOPIC X-RAY SYSTEMS

F.4.1 The requirements of F.3.2 for Certified Systems and Components shall apply to certified fluoroscopic x-ray systems and components, including radiation therapy simulation systems. Other fluoroscopic x-ray systems shall meet the requirements of the remainder of this subpart.

F.4.2 Limitation of Useful Beam.

(a) The fluoroscopic tube shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam at all times, and

(b) The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any source-image receptor distance (SID).

F.4.3 The x-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic procedures and spot filming procedures.

F.4.4 Image-intensified fluoroscopy and spot filming shall meet the following requirements:

(a) During fluoroscopic or spot-filming procedures, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(b) Compliance shall be determined with the beam axis perpendicular to the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

F.4.5 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

F.4.6 Exposure Rate Limits. The entrance exposure rate allowable limits are as follows:

(a) The equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images, or when an optional high level control is provided.

F.4.6 (b)

(b) When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(c) Compliance with the requirements of this section shall be determined as follows:

(1) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(2) If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle.

(3) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beamlimiting device or spacer positioned as closely as possible to the point of measurement.

(4) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

F.4.7 Periodic Measurement of Entrance Exposure Rate. Periodic measurement of entrance exposure rate shall be made annually or after any maintenance of the system which might affect the exposure rate. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in F.2.13 (e). Results of the measurements shall include the roentgen per minute, as well as the technique factors used to determine such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results. The measurements shall be made as follows:

(a) The measurements shall be made under conditions that satisfy the requirements of F.4.6 (c);

(b) The kVp shall be that typical of clinical use of the x-ray system;

(c) The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient material placed in the useful beam to produce operating parameters typical of the use of the x-ray system; and

(d) X-ray system(s) that do not incorporate an automatic exposure rate control shall utilize a milliamperage typical of the clinical use of the x-ray system.[1]

[1]Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

F.4.8 Barrier Transmitted Radiation Rate Limits. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

F.4.9 Measuring Compliance of Barrier Transmission. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

F.4.10 Indication of Potential and Current. During fluoroscopy and cinefluorography, the kilovoltage (kV) and the milliamperage (mA) shall be continuously indicated.

F.4.11 Source-Skin Distance. The source to skin distance shall not be less than:

(a) 38 centimeters on stationary fluoroscopes installed after the effective date of these regulations;

(b) 35.5 centimeters on stationary fluoroscopes which are in operation prior to the effective date of these regulations;

(c) 30 centimeters on all mobile fluoroscopes; and

(d) 20 centimeters for image intensified fluoroscopes used for specific surgical application. The users operating manual must provide precautionary measures to be adhered to during the use of this device.

F.4.12 Fluoroscopic Timer. Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

F.4.13 Mobile Fluoroscopes. In addition to the other requirements of subpart F.4, mobile fluoroscopes shall provide intensified imaging.

F.4.14 Control of Scattered Radiation.

(a) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(b) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual is at least 120 centimeters from the center of the useful beam, or the radiation has passed through not less than 0.25 millimeter lead equivalent material (e.g., drapes, Bucky-slot cover-sliding or folding panel, or self supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in section F.2.6. Exceptions may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exception.

F.5 X-RAY SYSTEMS OTHER THAN FLUOROSCOPIC, DENTAL INTRAORAL, OR VETERINARY SYSTEMS

F.5.1 Beam Limitation. The useful beam shall be limited to the area of clinical interest.

(a) For general purpose stationary and mobile x-ray systems there shall be provided a means for stepless adjustment of the size of the x-ray field. Means shall also be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam. The Agency may grant an exemption on non-certified x-ray systems, provided the registrant makes a written application for such exemption and in that application:

(1) Demonstrates that it is impractical to comply with these requirements, and

(2) Describes what other means will be used to achieve the purpose of this paragraph.

(b) In addition to the requirements of paragraph F.5.1 (a), all stationary x-ray systems shall meet the following requirements:

(1) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted; and

(3) Indication of field size dimensions and SID shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(c) X-ray equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID.

F.5.1 (d)

(d) Special purpcse x-ray systems shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Means shall also be provided to align the center of the x-ray field with the center of the image receptor tc within 2 percent of the SID. These requirements may be met with a system that meets the requirements for a general purpose x-ray system as specified in paragraph F.5.1 (a) or, when alignment means are also provided, may be met with either:

(1) As assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

F.5.2 Radiation Exposure Control Devices.

(a) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero.

(b) X-ray Control. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

(1) Exposure of one-half second or less, or

(2) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(c) Stationary x-ray systems shall be req[illegible] to have the x-ray control permanently mounted in a protected area s[illegible] the operator is required to remain in that protected area during the entire exposure. Mobile and portable x-ray systems which are used for greater than one week in one location shall meet the requirements of this paragraph.

F.5.3 Automatic Exposure Controls. When an automatic exposure control is provided:

(a) Indication shall be made on the control panel when this mode of operation is selected;

(b) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses and the minimum exposure time for all other equipment shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;

(c) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(d) A visible signal shall indicate when an exposure has been terminated at the limits required by paragraph F.5.3(b), and manual resetting shall be required before further automatically timed exposures can be made.

F.5.4 Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period ($\bar{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed using the same timer setting;

$$\text{i.e., } \bar{T} \geq 5(T_{max} - T_{min}).$$

F.5.5 Source-to-Skin Distance. All radiographic systems shall be provided with a durable, securely fastened means to limit the source-to-skin distance to not less than 30 centimeters.

F.5.6 Exposure Reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\bar{E}$) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min});

$$\text{i.e., } \bar{E} \geq 5(E_{max} - E_{min}).$$

F.5.7 Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

F.5.8 Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified components shall be required to comply with the requirements of section F.3.2.

F.5.9 Structural Shielding.

(a) All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of seven feet above the floor.

(b) Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

(c) The operator's station at the control shall be behind a protective barrier sufficient to assure compliance with section A.2.1. Provision shall be made for the operator to communicate with the patient from the operator's station.

(d) A window of lead equivalent glass equal to that of the adjacent barrier, or a mirror system shall be provided and it shall be large enough and so placed that the operator can see the patient during the exposure without having to leave the protected area.

F.6 INTRAORAL DENTAL X-RAY SYSTEMS

F.6.1 In addition to the provisions of subparts F.2 and F.3, the requirements of subpart F.6 apply to x-ray equipment and associated facilities used for dental radiography. Dental radiographic systems, when used with extraoral image receptors shall conform to the requirements of subpart F.5, except as specifically provided in section F.6.10.

F.6.2 Source-to-Skin Distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(1) 18 centimeters if operable above 50 kVp, or

(2) 10 centimeters if not operable above 50 kVp.

F.6.3 Field Limitation. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam. If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters. If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

F.6.4 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

F.6.5 Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed using the same timer setting;

$$\text{i.e., } \bar{T} \geq 5(T_{max} - T_{min}).$$

F.6.6 X-ray Control.

(a) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half second or less. The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(b) For stationary x-ray systems, it shall be required that the x-ray exposure switch be permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure. In addition, if the visual indication of x-ray production required by paragraph F.6.6 (a) is not observable from the operator's protected position, a visual indication of x-ray production shall be provided at the location of the x-ray exposure switch. Mobile and portable x-ray systems which are used for greater than one week in one location shall meet the requirements of this paragraph.

F.6.7 Exposure Reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met, if when 4 exposures are made at identical technique factors, the value of the average exposure ($\bar{E}$) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}).

$$\text{i.e., } \bar{E} \geq 5(E_{max} - E_{min}).$$

F.6.8 Administrative Controls.

(a) Patient and film holding devices shall be used when the techniques permit.

(b) Neither the tube housing nor the position indicating device shall be hand-held during an exposure.

(c) The x-ray system shall be operated in such a manner that the diameter of useful beam at the patient's skin does not exceed the requirements of section F.6.3.

(d) Dental fluoroscopy without image intensification shall not be used.

F.6.9 Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified components shall be required to comply with the requirements of section F.3.2.

F.6.10 Extraoral Procedures Utilizing Intraoral Dental X-ray Systems. When x-ray equipment designed for use with intraoral image receptors is used in combination with an extraoral image receptor, the requirements of subpart F.5 shall not apply, provided that:

(a) The procedure is conducted under the supervision of a licensed dental practitioner;

(b) The requirements of subpart F.6 are met;

(c) A film and screen combination of the fastest speed consistent with the diagnostic objective of the examination is used;

(d) The image receptor used is positioned to show evidence that the x-ray field in the plane of the image receptor has been confined to the image receptor.

F.7 THERAPEUTIC X-RAY SYSTEMS OF LESS THAN ONE MEV

F.7.1 Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that x-ray system.

(a) Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens per hour at 5 centimeters from the surface of the tube housing assembly.

(b) 0-150 kVp Systems. Systems which are manufactured or installed prior to the effective date of F.7 shall have a leakage radiation which does not exceed 1 roentgen in 1 hour at 1 meter from the source. Systems which are manufactured on or after the effective date of F.7 shall have a leakage radiation which does not exceed 100 milliroentgens in 1 hour at 1 meter from the source.

(c) 151 to 999 kVp Systems. The leakage radiation shall not exceed 1 roentgen in 1 hour at 1 meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source equivalent to the exposure within one hour of the useful beam at 1 meter from the source multiplied by a factor of 0.001.

F.7.2 Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or higher degree of protection as required by the tube housing assembly.

F.7.3 Removable and Adjustable Beam Limiting Devices. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the original x-ray beam at the maximum kilovoltage and maximum treatment filter. Adjustable beam limiting devices installed after the effective date of F.7 shall meet this requirement. Adjustable beam limiting devices installed before the effective date of F.7 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the original x-ray beam at the maximum kilovoltage and maximum treatment filter.

F.7.4 Filter System. The filter system shall be so designed that:

(a) Filters can not be accidently displaced from the useful beam at any possible tube orientation.

(b) Each filter shall be marked as to its material of construction and its thickness or wedge angle for wedge filters.

(c) It shall be possible for the operator to determine the presence or absence of each filter and the orientation of each wedge filter in the useful beam when the operator is at the control panel, either by display at the control panel or by direct observation.

(d) The radiation at 5 centimeters from the filter insertion slot opening shall not exceed 30 roentgens per hour under any operating conditions.

F.7. Tube Immobilization. The tube housing assembly shall be capable of being immobilized during stationary treatments.

F.7.6 Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

F.7.7 Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

F.7.8 Beam Monitor System. Systems of greater than 150 kVp manufactured after effective date of F.7 shall be provided with a beam monitor system which:

(a) Shall include a transmission detector which is a full beam detector and which is placed on the patient side of any fixed added filters other than a wedge filter;

(b) Shall have the detector interlocked to prevent incorrect positioning in the useful beam;

(c) Shall not allow irradiation until a pre-selected value of exposure of roentgens has been made at the treatment control panel;

(d) Shall independently terminate irradiation when the preselected number of roentgens has been reached;

(e) Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined.

(f) Shall have a display at the control panel from which reading in roentgens the dose at a reference point in the treatment volume can be calculated;

(g) Shall have a control panel display which maintains the reading until intentionally reset to zero; and

(h) Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

F.7.9 Timer. A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and fractions of minutes. The timer shall have a pre-set time selector and an elapsed time indicator.

(a) The timer shall be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to cycle the pre-set time selector through zero time.

(b) The timer shall terminate irradiation when a pre-selected time has elapsed.

(c) The timer shall permit accurate pre-setting and determination of exposure times as short as 1 second.

(d) The timer shall not permit an exposure if set at zero.

(e) The timer shall comply with the provisions of F.7.13 where applicable.

(f) The timer shall not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.

F.7.10 Control Panel Functions. The control panel, in addition to the displays required in other provisions of F.7 shall have:

(a) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

(b) An indication of whether x-rays are being produced;

(c) Means for indicating kV and x-ray tube current;

(d) The means for terminating an exposure at any time;

(e) A locking device which will prevent unauthorized use of the x-ray system; and

(f) For x-ray equipment manufactured after the effective date of F.7, a positive display of specific filter(s) in the beam.

F.7.11 Multiple Tubes. When a control panel may energize more than one x-ray tube:

(a) It shall be possible to activate only one x-ray tube during any time interval;

(b) There shall be an indication at the control panel identifying which x-ray tube is energized; and

(c) There shall be an indication at the tube housing assembly when that tube is energized.

F.7.12 Source-to-Patient Distance. There shall be a means of determining the source to patient distance to within 1 centimeter.

F.7.13 Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel. An indication of shutter position shall appear at the control panel.

F.7.14 Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

F.7.15 Facility Design Requirements for Systems Capable of Operating Above 50 kVp. In addition to shielding adequate to meet requirements of part A and part F of these regulations, the treatment room shall meet the following design requirements:

(a) Warning Lights. Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights, in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on."

(b) Voice Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel; however, where excessive noise levels make aural communication impractical, other methods of communication shall be used.

(c) Viewing Systems. Windows, mirrors, or closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. When the primary viewing system is by electronic means (e.g., television), an alternate viewing system shall be available for use in the event of electronic failure.

F.7.16 Additional Requirements. Treatment rooms which contain an x-ray system capable of operating above 150 kVp shall meet the following additional requirements:

(a) All necessary shielding, except for any beam interceptor, shall be provided by fixed barriers;

(b) The control panel shall be outside the treatment room;

(c) All doors of the treatment room shall be electrically connected to the control panel such that x-ray production cannot occur unless all doors are closed. When the doors are open while the x-ray tube is activated,

(1) X-ray production shall terminate within 1 second, or

(2) The radiation at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgens per hour within 1 second; and

(d) After the radiation output of the x-ray tube has been affected by the opening of any door referred to in (c), it shall be possible to restore the x-ray system to full operation only upon closing the door, and subsequently, reinitiating the exposure at the control panel.

F.7.17 Surveys. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. Such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. The expert shall report his findings in writing to the facility supervisor and a copy of the report shall be maintained by the registrant for inspection by the Agency. The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations and cite all items of non-compliance.

F.7.18 Calibrations.

(a) The calibration of an x-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.

(b) The calibration of the radiation output of the x-ray system shall be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration.

(c) Calibration of the radiation output of an x-ray system shall be performed with a calibrated instrument. The calibration of such instrument shall be directly traceable to a national standard. The instrument shall have been calibrated within the preceding 2 years.

(d) The calibrations made pursuant to this section shall be such that the dose at a reference point in soft tissue can be calculated to within ± 5 percent.

(e) The calibration of the x-ray system shall include, but not be limited to, the following determinations:

(1) Verification that the x-ray system is operating in compliance with the design specifications;

(2) The exposure rates for each combination of field size, technique factors, filter, and treatment distance used;

(3) The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and

(4) An evaluation of the uniformity of the radiation field symmetry for the field sizes used and any dependence upon tube housing assembly orientation.

(f) Records of calibration performed pursuant to this section shall be maintained by the registrant for 2 years after completion of the calibration.

(g) A copy of the most recent x-ray system calibration shall be available for use by the operator at the control panel.

F.7.19 Spot Checks. Spot-checks shall be performed on x-ray systems covered in this subpart. Such spot-checks shall meet the following requirements:

(a) The spot-check procedures shall be in writing and shall have been developed by a qualified expert;

(b) The measurements taken during the spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the x-ray system;

(c) The spot-check procedure shall be performed at least monthly.

(d) The procedure shall also note conditions which shall require that the system be recalibrated in accordance with F.7.18; and

(e) Records of spot-check measurements performed pursuant to this section shall be maintained by the registrant for 2 years following such measurement.

F.7.20 Operating Procedures.

(a) Therapeutic x-ray systems shall not be left unattended unless the system is secured pursuant to F.7.10 (e).

(b) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(c) The tube housing assembly shall not be held by an individual during exposures.

(d) No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of A.2.1 of these regulations. No individual other than the patient shall be in the treatment room during exposures when the kVp exceeds 150.

(e) The x-ray system shall not be used in the administration of radiation therapy unless the requirements of F.7.18 and F.7.19 (d) have been met.

F.8 X-RAY AND ELECTRON THERAPY SYSTEMS (1 MEV AND ABOVE)

All of the sections of part D except D.3.7 (c) and (d) shall apply to medical facilities using medical therapy equipment with energies 1 MeV and above.

F.8.1 Leakage Radiation to the Patient Area (equipment manufactured after August 1, 1978). For all operating conditions, the dose equivalent in rems due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the normal treatment distance and outside the maximum useful beam, shall not exceed 0.1 percent of the maximum dose equivalent in rem of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. For each system the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in this paragraph for specified operating conditions. Records on leakage radiation shall be maintained at the installation for inspection by the Agency.

F.8.2 Leakage Radiation to the Patient Area (equipment manufactured on or before August 1, 1978). The leakage radiation, excluding neutrons, at any point in the area specified by F.8.1 where such area intercepts the central axis of the beam 1 meter from the virtual source, shall not exceed 0.1 percent of the maximum dose equivalent in rem of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the referenced circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. For each system the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in F.8.1 for specified operating conditions. Records on leakage radiation shall be maintained at the installation for inspection by the Agency.

F.8.3 Leakage Radiation Outside the Patient Area. The dose equivalent in rem due to leakage radiation, except in the area specified in F.8.1, when measured at any point 1 meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.5 percent for neutron leakage of the maximum dose equivalent in rem of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in F.8.1. The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in this section for specified operating conditions. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

F.8.4 Beam Limiting Devices. Adjustable or interchangeable beam limiting devices shall transmit no more than 2 percent of the useful beam for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the normal treatment distance.

F.8.5 Filters. If the absorbed dose rate information required by F.8.17 relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools. In systems which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

(a) Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel.

(b) An interlock system shall be provided to prevent irradiation if the filter is not in the correct position.

(c) An indication at the control panel of the thin end of the wedge filter with respect to the treatment field shall be provided by direct observation or electronic means when wedge filters are used.

(d) A display shall be provided at the treatment control panel showing the filter(s) in use.

(e) Each filter which is removable from the system shall be clearly identified as to that filter's material of construction, thickness, and wedge angle for wedge filters.

(f) An interlock position shall be provided to prevent irradiation if any filter selection operations carried out in the treatment room do not agree with the selection operation carried out at the treatment control panel.

F.8.6 Beam Quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

(a) X-ray Stray Radiation In the Useful Electron Beam.

(1) The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table III. Linear interpolation shall be used for values not stated.

Table III

TABLE III

Maximum Energy of Electron Beam in MeV	X-ray Absorbed Dose a a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

(2) Compliance with F.8.6 (a) (1) shall be determined using:

(i) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

(ii) The largest field size available which does not exceed 15 centimeters by 15 centimeters; and

(iii) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

(b) Absorbed Dose at the Surface During X-ray Irradiation.

(1) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in Table IV. Linear interpolation shall be used for values not stated.

TABLE IV

Maximum Photon Energy in MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

(2) Compliance with F.8.6 (b) (1) shall be determined by:

(i) Measurements made with a phantom using an instrument which will allow extrapolation to the surface absorbed dose;

(ii) Use of a phantom whose size and placement meet the requirements of F.8.6 (a) (2); and

(iii) Removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters.

F.8.6 (c)

(c) Stray Radiation Information. The registrant shall determine, or obtain from the manufacturer, the absorbed dose due to stray neutrons in the useful beam for specified operating conditions.

F.8.7 Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head. Equipment manufactured after August 1, 1978, shall be provided with two radiation detectors in the radiation head. The two detectors shall be incorporated into two monitoring systems arranged either as a primary/primary combination or as a primary/secondary combination. Existing equipment shall be provided with at least one radiation detector in the radiation head. This detector shall be incorporated into a primary system. The detectors and system into which the detector is incorporated shall meet the following requirements:

(a) Each primary system shall have a detector which is a transmission detector and is a full beam detector and is placed on the patient side of any fixed added filters other than a wedge filter.

(b) The detectors shall be removable only with tools or shall be interlocked to prevent incorrect positioning.

(c) Each detector shall be capable of independently monitoring and controlling the useful beam.

(d) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated. For new equipment manufactured after August 1, 1978, the design of the dose monitoring systems shall assure that the malfunctioning of one system shall not affect the correct functioning of the second system. In addition:

(1) The failure of any element which may be common to both systems shall terminate the useful beam.

(2) The failure of the power supply of either dose monitoring system shall terminate the useful beam.

(e) Each dose monitoring system shall have a legible display at the treatment control panel. Each display shall:

(1) Maintain a reading until intentionally reset to zero.

(2) Have only one scale and no scale multiplying factors in equipment manufactured after August 1, 1978.

(3) Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that in the event of an overdosage of radiation the absorbed dose may be accurately determined under all normal conditions of use or foreseeable failures.

(f) In the event of power failure, dose monitoring information required in F.8.7 (e) displayed at the control panel at the time of failure shall be retrievable in at least one system.

F.8.8 Beam Symmetry. For equipment manufactured after August 1, 1978, each therapy machine shall have the capability of determining that the dose rates in each of the four quadrants of the useful beam are within 5% of each other in 80% of the central area of the field. An indication of beam symmetry shall appear at the control panel. Beam asymmetry in excess of 20 percent shall automatically terminate the useful beam. Beam symmetry requirements may be met if the user can demonstrate to the satisfaction of the Agency that adequate fail-safe protection against the beam asymmetry is incorporated into the inherent design of the accelerator. On existing equipment where the Agency has determined that beam symmetry is inadequate the use of an automatic beam asymmetry warning system may be required.

F.8.9 Selection and Display of Dose Monitor Units.

(a) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

(b) After useful beam termination it shall be necessary to reset manually the preselected dose monitor units before treatment can be reinitiated.

(c) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset for the next irradiation.

F.8.10 Termination of Irradiation by the Dose Monitoring System.

(a) Each of the required monitoring systems shall be capable of independently terminating irradiation. Provisions shall be made to test the correct operation of each system.

(b) Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

(c) Each secondary system shall terminate irradiation when the preselected number of dose monitor units plus 10 dose monitor units have been detected by the system.

(d) For equipment manufactured after August 1, 1978, indicators on the control panel shall show which monitoring system has terminated the beam.

F.8.11 Termination Switches. It shall be possible to terminate irradiation and equipment movements or go from an interruption condition to termination conditions at any time from the operator's position at the treatment control panel.

F.8.12 Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption the equipment shall go to termination condition.

F.8.13. Timer. A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and decimals of minutes. The timer shall have a preset time selector and an elapsed time indicator.

F.8.13 (a)

(a) The timer shall be a cumulative timer which switches on and off with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero the elapsed time indicator and the pre-set time selector after irradiation is terminated and before irradiation shall again be possible.

(b) The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems fail to do so.

F.8.14 Selection of Radiation Type. In equipment capable of both x-ray therapy and electron therapy:

(a) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel.

(b) An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.

(c) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(d) An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when x-ray wedge filters are fitted.

(e) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

F.8.15 Selection of Energy. In equipment capable of generating radiation beams of different energies:

(a) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

(b) An interlock system shall be provided to insure that the equipment can emit only the energy of radiation which has been selected.

(c) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(d) The energy selected shall be displayed at the treatment control panel before and during irradiation.

F.8.16 Selection of Stationary Beam Therapy or Moving Beam Therapy. In equipment capable of both stationary beam therapy and moving beam therapy:

(a) Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

(b) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.

(c) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(d) An interlock system shall be provided to terminate irradiation if the movement stops during moving beam therapy.

(e) Moving beam therapy shall be so controlled that the required relationship between the number of dose monitor units and movement is obtained.

(f) The mode of operation shall be displayed at the treatment control panel.

F.8.17 Absorbed Dose Rate. For equipment manufactured after August 1, 1978, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in F.8.7 may form part of this system. In addition:

(a) The quotient of the number of dose monitor units by time shall be displayed at the treatment control panel.

(b) If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer's anticipated dose rate for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be a record maintained by the registrant.

F.8.18 Location of Focal Spot and Beam Orientation. The registrant shall determine or obtain from the manufacturer the location with reference to an accessible point on the radiation head of:

(a) The x-ray target or the virtual source of x-rays.

(b) The electron window or the scattering foil.

(c) All possible orientations of the useful beam.

F.8.19 System Checking Facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked. When pre-selection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

F.8.20 Shadow trays shall be designed such that the skin entrance dose due to electrons produced within the shadow tray is minimized.

F.8.21 Facility and Shielding Requirements. In addition to shielding adequate to meet requirements of part A of these regulations the following design requirements are made:

(a) Except for entrance doors all the required barriers shall be fixed barriers.

(b) The treatment control panel shall be located outside the treatment room or within a protective booth equipped with an interlocked door which is electrically connected to the control panel in such a fashion that the door must be closed during radiation production.

(c) Windows, mirror systems, closed-circuit television viewing screens or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient from the treatment control panel. When the viewing system is by electronic means (e.g. television), an alternate viewing system shall be provided for use in the event of failure of the primary system.

(d) Provision shall be made for two-way aural communication with the patient from the control station. However where excessive noise levels makes aural communication impractical, other methods of communication shall be used.

(e) Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on."

(f) Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.

F.8.22 Protection Survey. Within 90 days of the effective date of these regulations, all existing facilities subject to subpart F.8 which have not previously been surveyed shall have a protection survey made by or under the direction of a qualified expert. New facilities shall have such a protection survey conducted prior to use for treatment. Such a survey shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. The registrant shall obtain a written report of the survey from the qualified expert and a copy of the report shall be transmitted by the registrant to the Agency. The survey and report shall indicate all instances where the installation in the opinion of the qualified expert is in violation of applicable therapy radiation protection regulations and shall cite the sections violated.

F.8.23 No person other than the patient shall be in the treatment room during treatment. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

F.8.24 Calibrations. The calibration of systems subject to F.8 shall be performed before any system is first used for irradiation of patients. The calibration shall be performed under the direct supervision of a qualified expert. Calibrations shall be repeated at least once every 6 months and after any change which might significantly change the calibration or spatial distribution or other characteristics of the machine output. Calibration of the dose equivalent of the therapy beam shall be performed with a measurement instrument the calibration of which is directly traceable to national standards of exposure or absorbed dose, and which shall have been calibrated within the preceding two years. Records of calibrations shall be maintained by the registrant. A copy of the latest calibration performed pursuant to this section shall be available for use by the operator at the treatment control panel. The calibration shall include at least the following determinations:

(a) Verification that the equipment is operating in compliance with design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter; when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at the specified depths.

(b) The exposure rate or dose rate in air and at various depths of water or water equivalent material for the range of field sizes used, for each effective energy and for each treatment distance used for radiation therapy.

(c) The congruence between the radiation field and the field indicated by the localizing device.

(d) The uniformity of the radiation field and its dependency upon the direction of the useful beam.

(e) The above calibrations shall be such that the dose at a reference point in soft tissue can be calculated within $\pm$ 5 percent.

F.8.25 Spot Checks. Spot checks shall be performed on systems subject to F.8. Spot checks shall meet the following requirements:

(a) The spot check procedures shall be in writing and shall have been developed by a qualified expert.

(b) The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure.

(c) The spot check procedures shall specify the frequency at which tests or measurements are to be performed.

(d) For systems in which beam quality can vary significantly, spot checks shall include quality checks.

(e) Where a system has built-in devices which provide a self-check of any parameter during irradiation, the spot check procedures shall require that the parameter be independently verified at specific time intervals.

(f) The reasons for spot checks which are erratic or inconsistent with calibration data shall be promptly investigated and corrected before the system is used for patient irradiation.

(g) Whenever a spot check indicates a significant change, as specified in the qualified expert's spot check procedures, in the operating characteristics of a system, the system shall be recalibrated as required in F.8.24.

(h) Records of spot check measurements performed pursuant to this section shall be maintained by the registrant for a period of one year.

F.9 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS

F.9.1 Equipment.

(a) The protective tube housing shall be equivalent to the requirements of F.3.5.

(b) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(c) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50-70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(d) A device shall be provided to terminate the exposure after a preset time or exposure.

(e) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet from the animal during all x-ray exposures.

F.9.2 Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with A.2.1, A.2.4, and A.2.5 of these regulations.

F.9.3 Operating Procedures.

(a) The operator shall stand well away from the useful beam and the animal during radiographic exposures.

(b) No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.

(c) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If necessary, general anesthesia, sedation or tranquilization should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. No individual shall be used routinely to hold animals or film during radiation exposures. The exposure of any individual used for this purpose shall be monitored, and a record shall be made of the examination, including the name of the human holder, date of the examination, number of exposures and technique factors utilized for the exposure(s).

PART F

APPENDIX A

INFORMATION TO BE SUBMITTED BY PERSONS
PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and where applicable, the names and addresses of agents within this State.

2. Diseases or conditions for which the x-ray examinations are to be used.

3. Description in detail of the x-ray examinations proposed in the screening program.

4 Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the x-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the x-ray system(s).

10. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

PART F

APPENDIX B

INSTRUCTION OF USERS OF X-RAY EQUIPMENT
IN THE HEALING ARTS

I. Fundamentals of Radiation Safety

A. Characteristics of x-radiation
B. Units of radiation dose (mrem)
C. Hazards of excessive exposure to radiation
D. Levels of radiation from sources of radiation
E. Methods of controlling radiation dose

1. Working time
2. Working distances
3. Shielding

II. Radiation Detection Instrumention to be Used

A. Radiation survey instruments

1. Operation
2. Calibration
3. Limitations

B. Survey, monitoring, and spot-check techniques
C. Personnel monitoring devices

1. Film badges
2. Pocket dosimeters
3. Thermoluminescent dosimeters

D. Interpretation of personnel monitoring reports

III. Operation and Control of X-ray Equipment

A. Collimation and Filtration
B. Exposure techniques for the equipment used
C. Film processing techniques
D. Anatomy and positioning

1. Relevant human anatomy
2. Relevant human physiology
3. Radiographic positioning

IV. The requirements of pertinent federal and state Regulations

V. The licensee's or registrant's written operating and emergency procedures

RHODE ISLAND RULES AND REGULATIONS

FOR THE

CONTROL OF RADIATION

ANNEX

Adopted 2 June 1978

RHODE ISLAND RULES AND REGULATIONS

FOR THE

CONTROL OF RADIATION

PART G

RADIATION SAFETY REQUIREMENTS FOR MICROWAVE OVENS

Adopted 2 June 1978

PART G

RADIATION SAFETY REQUIREMENTS FOR MICROWAVE OVENS

G.1 Purpose and Scope. The regulations in this part establish radiation safety requirements for microwave ovens which are designed to heat, cook, or dry food through the application of electromagnetic energy at frequencies assigned by the Federal Communications Commission in the normal ISM heating bands ranging from 890 megahertz to 6,000 megahertz.

G.2 Performance Standards. Microwave ovens manufactured after October 6, 1971, shall be maintained in compliance with the applicable federal performance standards for microwave ovens in Title 21, Code of Federal Regulations, Chapter I, Subchapter J.

G.3 Power Density Limits.

(a) The power density of the microwave radiation emitted by any microwave oven manufactured after October 6, 1971, shall not exceed one (1) milliwatt per square centimeter at any point 5 centimeters or more from the external surface of the oven, measured prior to acquisition by a purchaser, and thereafter, 5 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven.

(b) For ovens manufactured on or before October 6, 1971, the power density of the emitted microwave radiation shall not exceed 10 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven.

G.4 Non-Compliance. Any microwave oven which fails to meet the requirements of this part shall be removed from service until the repairs or modifications necessary to meet the applicable standard(s) have been made.

DEFINITIONS

1) Accelerator produced material means any material made radioactive by exposing it in a particle accelerator.

2) Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

3) Act means Title 23, Chapter 1.3 of the General Laws of the State of Rhode Island entitled Radiation Control.

4) Added filtration means any filtration which is in addition to the inherent filtration.

5) Agency means R. I. Radiation Control Agency, Division of Occupational Health, Rhode Island Department of Health.

6) Agreement State means any State with which the United States Nuclear Regulatory Commission has entered into an effective agreement under section 274 b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

7) Airborne radioactive material means any radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors, or gases.

8) Airborne radioactivity area means (1) any room, enclosure, or operating area in which airborne radioactive material exists in concentrations in excess of the amounts specified in Appendix A, Table I, Column 1 of part A; or (2) any room, enclosure, or operating area in which airborne radioactive 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 A, Table I, Column 1 of part A.

9) Aluminum equivalent means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question.

10) Analytical x-ray equipment means equipment used for x-ray diffraction or fluorescence analysis.

11) Analytical x-ray system means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

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[1]The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

12) Applicator means a structure which indicates the extent of the treatment field at a given distance from the virtual source and which may or may not incorporate the beam limiting device.

13) Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem.

14) Attenuation block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[1] or other materials having equivalent attenuation.

15) Automatic exposure control means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also Phototimer).

16) Barrier (See Protective barrier).

17) Beam axis means a line from the source through the centers of x-ray fields.

18) Beam-limiting device means a device which provides a means to restrict the dimensions of an x-ray field.

19) Beam scattering filter means a filter used in order to scatter a beam of electrons.

20) 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.

21) Cabinet radiography means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the conditions specified in A.2.5 of these regulations.

22) Cabinet x-ray system means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation. Included are all x-ray systems designed primarily for the inspection of carry-on facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

23) 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 so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of these regulations except at the beginning of a calendar year.

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[1]The nominal chemical composition of type 1100 aluminum alloy is 99.0 percent minimum aluminum, 0.12 percent copper.

24) Central axis of the beam means a line passing through the virtual source and the center of the plane figure formed by the edge of the final beam limiting device.

25) Certified cabinet x-ray system means an x-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFT 1020.40.

26) Certified components means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

27) Certified system means any x-ray system which has one or more certified component(s).

28) Changeable filters means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.

29) Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[\sum_{i=1}^{n} \frac{(X_i - \bar{X})^2}{n-1} \right]^{\frac{1}{2}}$$

where
s = Estimated standard deviation of the population.
$\bar{X}$ = Mean value of observations in sample.
X_i = ith observation in sample.
n = Number of observations in sample.

30) Contact therapy system means an x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

31) Control panel means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

32) Controlled area (See Restricted area).

33) Cooling curve means the graphical relationship between heat units stored and cooling time.

34) Curie means a unit of measurement of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegrations per second (dps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie = 3.7×10^{7} dps. One microcurie (uCi) = 0.000001 curie = 3.7×10^{4} dps.

35) Dead-man switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

36) Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

37) Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

38) Direct scattered radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See Scattered radiation).

39) Dose as used in these regulations shall mean absorbed dose or dose equivalent as appropriate.

> Absorbed dose is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the rad. (See rad.)
>
> Dose equivalent is a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. The unit of dose equivalent is the rem. (See rem.)

40) Dose monitor unit means a unit from which the absorbed dose can be calculated.

41) Dose monitoring system means a system of devices for the detection and display of quantities of radiation.

42) Enclosed radiography means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded room radiography.

43) Entrance exposure rate means the roentgens per unit time at the point where the center of the useful beam enters the patient.

44) Equipment (See X-ray equipment).

45) Exposure[2] means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. (The special unit of exposure is the roentgen.)

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[2]When the word "exposure" is used in part F to mean one or more irradiations of an individual for a healing arts purpose, or in a more general sense, it will not be underlined.

46) Exposure rate means the exposure per unit of time, such as R/min, mR/h, etc.

47) Fail-safe characteristics mean a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

48) Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

49) Field flattening filter means a filter used to homogenize the dose rate over the area of a useful beam of x-rays.

50) Field size means the dimensions of an area in a plane perpendicular to the specified direction of the beam of incident radiation at a specified depth in a phantom and defined by specified isodose lines.

51) Filter means material placed in the useful beam to absorb preferentially selected radiations.

52) Fluoroscopic imaging assembly means a component which comprises a reception system in which x-ray photons produce a fluoroscopic image. It includes equipment housings, electrical interlocks if any, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.

53) Gantry means that part of the system supporting and allowing possible movements of the radiation head.

54) General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

55) Gonadal shield means a protective barrier for the testes or ovaries.

56) Half-value layer means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

57) Healing Arts, as used in these regulations, means any discipline which involves the diagnosis or treatment of individuals by a practitioner who is licensed for that purpose by the State of Rhode Island, and which discipline, prior to the effective date of these regulations, included the intentional exposure of individuals to sources of radiation for diagnosis or treatment.

58) Healing arts screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

59) Heat unit means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

60) High radiation area means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirems.

61) Human use means the internal or external administration of radiation or radioactive material to human beings.

62) HVL (See Half-value layer).

63) Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

64) Image receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

65) Individual means any human being.

66) Industrial radiography means the examination of the macroscopic structure of materials by nondestructive methods utilizing sources of radiation.

67) Inherent filtration means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

68) Inspection means an official examination or observation including but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the Agency.

69) Interlock means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

70) Interruption of irradiation means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

71) Isocenter means a fixed point in space located at the intersection of the rotation axes of the principal movements of the therapy system.

72) Kilovolts peak (See Peak tube potential).

73) kVp (See Peak tube potential).

74) kWs means kilowatt second which is equal to the product of peak kilovolts, amperes, and seconds, e.g., 10^3kV mA sec.

75) Lead equivalent means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

76) Leakage radiation means radiation emanating from the diagnostic or therapeutic source assembly except for:

(a) the useful beam, and

(b) radiation produced when the exposure switch or timer is not activated.

77) Leakage technique factors means the technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:

(a) For capacitor energy storage equipment, the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

(b) For field emission equipment rated for pulsed operation, the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.

(c) For all other equipment, the maximum rated continuous tube current for the maximum rated peak tube potential.

78) License means a license issued by the Agency in accordance with the regulations adopted by the Agency.

79) Licensee means any person who is licensed by the Agency in accordance with these regulations and the Act.

80) Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

81) Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100\ (V_n - V_1)/V_1$$

where

V_n = No-load line potential and

V_1 = Load line potential.

82) Maximum line current means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

83) Mobile equipment (See X-ray equipment).

84) Moving beam therapy means radiation therapy with relative displacement of the useful beam and the patient during irradiation.

85) Natural radioactivity means radioactivity of naturally occurring nuclides.

86) Normal operating procedures mean operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.

87) Normal treatment distance means the distance between the virtual source and a reference point on the central axis of the beam. The reference point is located at a position where the patient will be placed during radiation therapy.

88) Occupational dose means exposure of an individual to radiation (1) in a restricted area; or (2) 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 diagnosis or therapy of such individual.

89) Open-beam configuration means an analytical x-ray system in which an individual could accidently place some part of his body in the primary beam path during normal operation.

90) Order of abatement means a legal order of the Administrator pursuant to Chapter 23-1.3-8 of the General Laws of the State of Rhode Island requiring that the person to whom the order is issued shall, prior to a time fixed by the Administrator, which time shall not be later than ten days from the date of service of the order, cease and abate causing, allowing, or permitting violation(s) and take such action as may be necessary to comply with this chapter and codes, rules or regulations promulgated thereunder.

91) Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

92) Patient means an individual subjected to examination and treatment.

93) Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

94) Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, and other State or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing.

95) Personal supervision means supervision such that the supervisor is physically present at the radiography site and in such proximity that contact can be maintained and immediate assistance given as required.

96) Personnel monitoring equipment means devices (e.g. film badges, pocket dosimeters, and thermoluminescent dosimeters) designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual.

97) Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

98) Pharmacist means an individual licensed by this State to compound and dispense drugs, prescriptions, and poisons.

99) Phototimer means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See Automatic exposure control).

100) Physician means a person with a license to practice allopathic or osteopathic medicine in this State under Rhode Island general laws.

101) PID (See Position indicating device).

102) Position indicating device means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

103) Primary beam means ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

104) Primary dose monitoring system means a system which will monitor the quantity of radiation produced during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

105) Primary protective barrier (See Protective barrier).

106) Protective apron means an apron made of raciation absorbing materials used to reduce radiation exposure.

107) Protected area means an area which provides radiation protection to x-ray equipment operators, sufficient to assure compliance with part A under all operating conditions.

108) Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure pursuant to the requirements of part A of these regulations. The types of protective barriers are as follows:

(a) Primary protective barrier means the material(s), excluding filters, placed in the useful beam for radiation protection purposes.

(b) Secondary protective barrier means a barrier of radiation absorbing material(s) providing protection from stray radiation exposure.

109) Protective glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

110) Qualified expert means an individual who has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

111) Rad means the special unit of absorbed dose. One rad equals one hundreth of a joule per kilogram of material; for example, if tissue is the material of interest, then 1 rad equals 100 ergs per gram of tissue.

112) Radiation means (1) ionizing radiation, i.e., gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles; (2) any electromagnetic radiation which can be generated during the operation of a microwave oven.

113) Radiation area means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 millirems, or in any 5 consecutive days a dose in excess of 100 millirems.

114) Radiation head means the structure from which the useful beam emerges.

115) Radiation machine means any device capable of producing radiation except those which produce radiation only from radioactive material.

116) Radiation safety officer (radiation protection designee) means one who has the knowledge and responsibility to apply appropriate radiation protection regulations.

117) Radiation treatment prescription means the absorbed dose which is intended to be delivered to the treatment volume.

118) Radioactive material means any material (solid, liquid, or gas) which emits radiation spontaneously.

119) Radioactivity means the disintegration of unstable atomic nuclei by the emission of radiation.

120) Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

121) Radiographer means any individual who performs, or provides personal supervision of, industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these regulations and all license and/or certificate of registration conditions.

122) Radiographer's assistant means any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or survey instruments in industrial radiography.

123) Radiographic exposure device means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

124) Radiographic imaging system means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

125) Rating means the operating limits as specified by the component manufacturer.

126) Recording means producing a permanent form of an image resulting from x-ray photons (e.g., film, video tape).

127) Redundant dose monitoring combination means a combination of two dose monitoring systems in which both systems are arranged to terminate irradiation in accordance with a pre-selected number of dose monitor units.

128a) Registrant means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to these regulations and the Act.

128b) Registrant as used in part B, means any person who owns or possesses and administratively controls an x-ray system or particle accelerator, and any person who is engaged in the business of installing or offering to install radiation equipment or is engaged in the business of furnishing or offering to furnish x-ray equipment servicing or services, and are required by part B of these regulations to register with the Agency.

129) Registration means registration with the Agency in accordance with the regulations adopted by the Agency.

130) Regulations of the U.S. Department of Transportation means the regulations in 49 CFR Parts 170-189, 14 CFR Part 103, and 46 CFR Part 146.

131) Rem means a measure of the dose of any radiation to body tissue in terms of its estimated biological effect relative to a dose received from an exposure to one roentgen (R) of x-rays. (One millirem (mrem) = 0.001 rem.) For the purpose of these regulations, any of the following is considered to be equivalent to a dose of one rem:

(1) An exposure of 1 R of X, or gamma radiation;
(2) A dose of 1 rad due to X, gamma, or beta radiation;
(3) A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye;
(4) A dose of 0.1 rad due to neutrons or high energy protons.

132) Research and development means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

133) Research and development x-ray equipment means equipment generating x-radiation for research and development purposes.

134) Research and development x-ray system means a group of local and remote components utilizing x-rays for research and development purposes. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices and control panels.

135) Response time means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid-scale reading.

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

137) Roentgen (R) means the special unit of exposure. One roentgen equals 2.58×10^{-4} coulombs/kilogram of air (see Exposure).

138) Scattered radiation means radiation that, during passage through matter, has been deviated in direction (see Direct scattered radiation).

139) Sealed source means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

140) Secondary dose monitoring system means a system which will terminate irradiation in the event of failure of the primary system.

141) Secondary protective barrier (See Protective barrier).

142) Shadow tray means a device attached to the radiation head to support auxiliary beam limiting material.

143) Shielded position means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

144) Shielded-room radiography means industrial radiography conducted in a room so shielded that every location on the exterior meets the conditions specified in A.2.5 of these regulations.

145) Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

146) Source means the focal spot of the x-ray tube.

147) Source-image receptor distance (SID) means the distance from the source to the center of the input surface of the image receptor.

148) Source material means (1) uranium or thorium, or any combination thereof, in any physical or chemical form, or (2) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (i) uranium, (ii) thorium, or (iii) any combination thereof. Source material does not include special nuclear material.

149) Source of radiation means any radioactive material, or any device or equipment emitting or capable of producing radiation.

150) Special form means any of the following forms of licensed material of any transport group:

(a) The material is in solid form having no dimension less than 0.5 millimeter or at least one dimension greater than five millimeters; does not melt, sublime, or ignite in air at a temperature of 1,000°F.; will not shatter or crumble if subjected to the percussion test described in Appendix E of part A, and is not dissolved or converted into dispersible form to the extent of more than 0.005 percent by weight by immersion for 1 week in water at 68° F. or in air at 86°F.; or

(b) The material is securely contained in a capsule having no dimension less than 0.5 millimeter or at least one dimension greater than five millimeters, which will retain its contents if subjected to the tests prescribed in Appendix E of part A; and which is constructed of materials which do not melt, sublime, or ignite in air at 1,475°F., and do not dissolve or convert into dispersible form to the extent of more than 0.005 percent by weight by immersion for 1 week in water at 68°F. or in air at 86°F.

151) Special nuclear material in quantities not sufficient to form a critical mass means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

152) Spot film means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

153) Storage container means a device in which sealed sources are transported or stored.

154) Stationary beam therapy means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

155) Stationary equipment (See X-ray equipment).

156) Stray radiation means the sum of leakage and scattered radiation.

157) Survey means an evaluation of the production, use, release, disposal, and/or presence of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to tests, physical examination and measurements of levels of radiation or concentration of radioactive material present.

158) Target means that part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

159) Technique factors means the conditions of operation. They are specified as follows:

(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.

(c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

160) Termination of irradiation means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

161) Test means a method for determining the characteristics or condition of sources of radiation or components thereof.

162) These regulations mean all parts of Rhode Island Rules and Regulations for the Control of Radiation.

163) Transport group means any one of seven groups into which radionuclides in normal form are classified, according to their toxicity and their relative potential hazard in transport, in Appendix D of part A.

(1) Any radionuclide not specifically listed in one of the groups in part A, Appendix D shall be assigned to one of the groups in accordance with the following table:

	Radioactive half-life		
Radionuclide	0 to 1000 days	1000 days to 10^6 years	Over 10^6 years
Atomic number 1-81	Group III	Group II	Group III
Atomic number 82 and over	Group I	Group I	Group III

(2) For mixtures of radionuclides the following shall apply:

(a) If the identity and respective activity of each radionuclide are known, the permissible activity of each radionuclide shall be such that the sum, for all groups present, of the ratio between the total activity for each group to the permissible activity for each group will not be greater than unity.

(b) If the groups of the radionuclides are known but the amount in each group cannot be reasonably determined, the mixture shall be assigned to the most restrictive group present.

(c) If the identity of all or some of the radionuclides cannot be reasonably determined, each of those unidentified radionuclides shall be considered as belonging to the most restrictive group which cannot be positively excluded.

(d) Mixtures consisting of a single radioactive decay chain where the radionuclides are in the naturally occurring proportions shall be considered as consisting of a single radionuclide. The group and activity shall be that of the first member present in the chain, except that if a radionuclide "X" has a half-life longer than that of the first member and an activity greater than that of any other member, including the first, at any time during transportation, the transport group of the nuclide "X" and the activity of the mixture shall be the maximum activity of that nuclide "X" during transportation.

164) Treatment field means the area of the patient's skin which is to be irradiated.

165) Tube means an x-ray tube, unless otherwise specified.

166) Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

167) Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

168) Unrefined and unprocessed ore means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

169) Unrestricted area (uncontrolled area) means any area access to which is not controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material, and any area used for residential quarters.

170) Useful beam means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

171) Variable-aperture beam-limiting device means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

172) Virtual source means a point from which radiation appears to originate.

173) Visible area means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.

174) Worker means an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

175) X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment which controls the technique factors of an x-ray exposure.

176) X-ray equipment means an x-ray system, subsystem, or major component thereof. (Examples of major components are: tube housing assemblies, x-ray controls, x-ray high voltage generators, fluoroscopic imaging assemblies, tables, cradles, film changers, cassette holders and beam limiting devices.) Types of x-ray equipment are as follows:

(a) Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

(b) Portable x-ray equipment means x-ray equipment designed to be hand-carried.

(c) Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

177) X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

178) X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

179) X-ray subsystem means any combination of two or more components of an x-ray system.

180) X-ray system means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

181) X-ray tube means any electron tube which is designed to be used primarily for the production of x-rays.

FORM RCA-1

RHODE ISLAND RADIATION CONTROL AGENCY

NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION: NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTIONS

IN THE RHODE ISLAND RULES AND REGULATIONS FOR THE CONTROL OF RADIATION, THE RHODE ISLAND RADIATION CONTROL AGENCY HAS ESTABLISHED STANDARDS FOR YOUR PROTECTION AGAINST RADIATION HAZARDS. IN THE RHODE ISLAND RULES AND REGULATIONS FOR THE CONTROL OF RADIATION, THE RHODE ISLAND RADIATION CONTROL AGENCY HAS ESTABLISHED CERTAIN PROVISIONS FOR THE OPTIONS OF WORKERS ENGAGED IN WORK UNDER AN AGENCY LICENSE OR REGISTRATION.

YOUR EMPLOYER'S RESPONSIBILITY

YOUR EMPLOYER IS REQUIRED TO--

1. APPLY THESE REGULATIONS TO WORK INVOLVING SOURCES OF RADIATION.
2. POST OR OTHERWISE MAKE AVAILABLE TO YOU A A COPY OF THE RHODE ISLAND RADIATION CONTROL AGENCY REGULATIONS, AND THE OPERATING PROCEDURES WHICH APPLY TO WORK YOU ARE ENGAGED IN, AND EXPLAIN THEIR PROVISIONS TO YOU.
3. POST NOTICE OF VIOLATION INVOLVING RADIOLOGICAL WORKING CONDITIONS, PROPOSED IMPOSITION OF CIVIL PENALTIES AND ORDERS.

WHAT IS COVERED BY THESE REGULATIONS

1. LIMITS ON EXPOSURE TO RADIATION AND RADIOACTIVE MATERIAL IN RESTRICTED AND UNRESTRICTED AREAS;
2. MEASURES TO BE TAKEN AFTER ACCIDENTAL EXPOSURE;
3. PERSONNEL MONITORING, SURVEYS AND EQUIPMENT;
4. CAUTION SIGNS, LABELS, AND SAFETY INTERLOCK EQUIPMENT;
5. EXPOSURE RECORDS AND REPORTS;
6. OPTIONS FOR WORKERS REGARDING AGENCY INSPECTIONS; AND
7. RELATED MATTERS.

YOUR RESPONSIBILITY AS A WORKER

YOU SHOULD FAMILIARIZE YOURSELF WITH THOSE PROVISIONS OF THE RHODE ISLAND RADIATION CONTROL AGENCY REGULATIONS, AND THE OPERATING PROCEDURES WHICH APPLY TO THE WORK YOU ARE ENGAGED IN. YOU SHOULD OBSERVE THEIR PROVISIONS FOR YOUR OWN PROTECTION AND PROTECTION OF YOUR CO-WORKERS.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. THE RHODE ISLAND RADIATION CONTROL AGENCY REGULATIONS REQUIRE THAT YOUR EMPLOYER GIVE YOU A WRITTEN REPORT IF YOU RECEIVE AN EXPOSURE IN EXCESS OF ANY APPLICABLE LIMIT AS SET FORTH IN THE REGULATIONS OR IN THE LICENSE. THE BASIC LIMITS FOR EXPOSURE TO EMPLOYEES ARE SET FORTH IN SECTIONS A.2.1, A.2.3, AND A.2.4 OF THE REGULATIONS. THESE SECTIONS SPECIFY LIMITS ON EXPOSURE TO RADIATION AND EXPOSURE TO CONCENTRATIONS OF RADIOACTIVE MATERIAL IN AIR.
2. IF YOU WORK WHERE PERSONNEL MONITORING IS REQUIRED,
   A. YOUR EMPLOYER MUST GIVE YOU A WRITTEN REPORT, UPON TERMINATION OF YOUR EMPLOYMENT, OF YOUR RADIATION EXPOSURES, AND
   B. YOUR EMPLOYER MUST ADVISE YOU ANNUALLY OF YOUR EXPOSURE TO RADIATION.

INSPECTIONS

ALL LICENSED OR REGISTERED ACTIVITIES ARE SUBJECT TO INSPECTION BY REPRESENTATIVES OF THE RHODE ISLAND RADIATION CONTROL AGENCY. IN ADDITION, ANY WORKER OR REPRESENTATIVE OF WORKERS WHO BELIEVES THAT THERE IS A VIOLATION OF THE RADIATION CONTROL ACT, THE REGULATIONS ISSUED THEREUNDER, OR THE TERMS OF THE EMPLOYER'S LICENSE OR REGISTRATION WITH REGARD TO RADIOLOGICAL WORKING CONDITIONS IN WHICH THE WORKER IS ENGAGED, MAY REQUEST AN INSPECTION BY SENDING A NOTICE OF THE ALLEGED VIOLATION TO THE RHODE ISLAND RADIATION CONTROL AGENCY. THE REQUEST MUST SET FORTH THE SPECIFIC GROUNDS FOR THE NOTICE, AND MUST BE SIGNED BY THE WORKER AS THE REPRESENTATIVE OF THE WORKERS. DURING INSPECTIONS, AGENCY INSPECTORS MAY CONFER PRIVATELY WITH WORKERS, AND ANY WORKER MAY BRING TO THE ATTENTION OF THE INSPECTORS ANY PAST OR PRESENT CONDITION WHICH HE BELIEVES CONTRIBUTED TO OR CAUSED ANY VIOLATION AS DESCRIBED ABOVE.

POSTING REQUIREMENT

COPIES OF THIS NOTICE MUST BE POSTED IN A SUFFICIENT NUMBER OF PLACES IN EVERY ESTABLISHMENT WHERE EMPLOYEES IN ACTIVITIES LICENSED OR REGISTERED, PURSUANT TO PART B OR PART C, BY THE RHODE ISLAND RADIATION CONTROL AGENCY, TO PERMIT EMPLOYEES WORKING IN OR FREQUENTING ANY PORTION OF A RESTRICTED AREA TO OBSERVE A COPY ON THE WAY TO OR FROM THEIR PLACE OF EMPLOYMENT.

RHODE ISLAND RADIATION CONTROL AGENCY

OCCUPATIONAL EXTERNAL RADIATION EXPOSURE HISTORY

IDENTIFICATION

1. NAME: (Print-last, first, and middle)	2. SOCIAL SECURITY NO.:
3. DATE OF BIRTH: (Month, Day, Year)	4. AGE IN FULL YEARS (N)

OCCUPATIONAL EXPOSURE - PREVIOUS HISTORY

5. PREVIOUS EMPLOYMENTS INVOLVING RADIATION EXPOSURE-LIST NAME AND ADDRESS OF EMPLOYER	6. DATES OF EMPLOYMENT (FROM - TO)	7. PERIODS OF EXPOSURE	PREVIOUS DOSE HISTORY	
			8. WHOLE BODY (REM)	9. RECORD OR CALCULATED (INSERT ONE)

10. REMARKS	11. ACCUMULATED OCCUPATIONAL DOSE - TOTAL	

12. CALCULATIONS - PERMISSIBLE DOSE

WHOLE BODY:

(A) Permissible Accumulated Dose - 5(N - 18) _____ Rem

(B) Total Exposure to Date (From Item 11) _____ Rem

(C) Unused Part of Permissible Accumulated Dose (A-B) _____ Rem

12. CERTIFICATION: I CERTIFY THAT THE EXPOSURE HISTORY LISTED IN COLUMNS 5, 6, AND 7 IS CORRECT AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

_____
Employee's Signature Date

14. _____
NAME OF LICENSEE OR REGISTRANT

FORM RCA-2

492 077

INSTRUCTIONS FOR PREPARATION OF AGENCY FORM RCA-2

This form or a clear and legible record containing all the information required on this form must be prepared by each licensee or registrant of the Rhode Island Radiation Control Agency who, pursuant to section A.2.1, proposes to expose an individual to a radiation dose in excess of the amounts specified in paragraph A.2.1 (a) of the regulations in part A "Standards for Protection Against Radiation." The requirement for completion of this form is contained in section A.2.2 of that regulation. The information contained in this form is used for estimating the external accumulated occupational dose of the individual for whom the form is completed. A separate Agency Form RCA-2 shall be completed for each individual to be exposed to a radiation dose in excess of the limits specified in paragraph A.2.1 (a) of part A of the Rhode Island Radiation Control Agency regulations.*

Listed below by item are instructions and additional information directly pertinent to completing this form:

Identification.

Item 1. Self-explanatory.

Item 2. Self-explanatory except that, if individual has no social security number, the word "none" shall be inserted.

Item 3. Self-explanatory.

Item 4. Enter the age in full years. This is called "N" when used in calculating the Permissible Dose. N is equal to the number of years of age of the individual on his last birthday.

Occupational Exposure.

Item 5. List the name and address of each previous employer and the address of employment. Start with the most recent employer and work back. Include only those periods of employment since the eighteenth birthday involving occupational exposure to radiation. For periods of self-employment, insert the word "self-employed."

Item 6. Give the dates of employment.

Item 7. List periods during which occupational exposure to radiation occurred.

Item 8. List the dose recorded for each period of exposure from records of previous occupational exposure of the individual as calculated under section A.2.2. Dose is to be given in rem. "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.

Item 9. After each entry in Item 8 indicate in Item 9 whether dose is obtained from records or calculated in accordance with section A.2.2.

Item 10. Self-explanatory.

*This form requires the signature of the employee concerned.

Total Accumulated Occupational Dose (Whole Body).

Item 11. The total for the whole body is obtained by summation of all values in Item 8.

Certification.

Item 12. Upon completion of the report, the employee must certify that the information in Columns 5, 6, and 7 is accurate and complete to the best of his knowledge. The date is the date of his signature.

Calculations.

Item 13. The lifetime accumulated occupational dose for each individual and the permissible dose under paragraph A.2.1 (b) are obtained by carrying out the following steps: The value for N should be taken from Item 4. Subtract 18 from N and multiply the difference by 5 rem. (For example, John Smith, age 32; N = 32, PAD = 5(32-18) = 70 rem.) Enter total exposure to date from Item 11. Subtract (b) from (a) and enter the difference under (c). The value in (c) represents the unused part of the permissible accumulated dose. This value for permissible dose is to be carried forward to Agency Form RCA-3, "Current Occupational External Radiation Exposure (Whole Body)."

Item 14. Self-explanatory.

RHODE ISLAND RADIATION CONTROL AGENCY

CURRENT OCCUPATIONAL EXTERNAL RADIATION EXPOSURE

IDENTIFICATION

1. NAME: (Print-last, first, and middle)	2. SOCIAL SECURITY NO.:
3. DATE OF BIRTH: (Month, Day, Year)	4. NAME OF LICENSEE OR REGISTRANT:

OCCUPATIONAL EXPOSURE

5. DOSE RECORDED FOR (Specify: Whole body, skin of whole body, or hands and forearms, feet and ankles)	6. WHOLE BODY DOSE STATUS (Rem)	7. METHOD OF MONITORING (e.g., Film Badge-FB, Pocket Chamber-PC; Calculations-Calc.) X or Gamma_____ Beta_____ Neutrons_____

8. PERIOD OF EXPOSURE: From - To	DOSE FOR THE PERIOD (Rem)				13. RUNNING TOTAL FOR CALENDAR QUARTER (Rem)
	9. X or γ	10. Beta	11 Neutron	12. Total	

LIFETIME ACCUMULATED DOSE

14. PREVIOUS TOTAL (Rem)	15. TOTAL QUARTERLY DOSE Date Rem	16. TOTAL ACCUMULATED DOSE (Rem)	17. PERM. ACC. DOSE 5(N-18) (Rem)	18. UNUSED PART OF PERMISSIBLE ACCUMULATED DOSE (Rem)

FORM RCA-3

Y92 050

INSTRUCTIONS FOR PREPARATION OF AGENCY FORM RCA-3

The preparation and safekeeping of this form or a clear and legible record containing all the information required on this form is required pursuant to section A.5.1 of "Standards for Protection Against Radiation," part A, as a current record of occupational external radiation exposures. Such a record must be maintained for each individual for whom personnel monitoring is required under section A.3.2. Note that a separate Agency Form RCA-3 is to be used for recording external exposure to (1) the whole body; (2) skin of whole body; (3) hands and forearms; or (4) feet and ankles, as provided by Item 5 below.

Listed below by item are instructions and additional information directly pertinent to completing this form.

Identification.

Item 1. Self-explanatory.

Item 2. Self-explanatory except that, if individual has no social security number, the word "none" shall be inserted.

Item 3. Self-explanatory.

Item 4. Self-explanatory.

Occupational Exposure.

Item 5. "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. Unless the lenses of the eyes are protected with eye shields, dose recorded as whole body dose should include the dose delivered through a tissue equivalent absorber having a thickness of 300 mg/cm^2 or less. When the lenses of the eyes are protected with eye shields having a tissue equivalent thickness of at least 700 mg/cm^2, dose recorded as whole body dose should include the dose delivered through a tissue equivalent absorber having a thickness of 1,000 mg/cm^2 or less.

Dose recorded as dose to the skin of the whole body, hands and forearms, or feet and ankles should include the dose delivered through a tissue equivalent absorber having a thickness of 7 mg/cm^2 or less. The dose to the skin of the whole body, hands and forearms, or feet and ankles should be recorded on separate forms unless the dose to those parts of the body has been included as dose to the whole body on a form maintained for recording whole body exposure.

Item 6. This item need be completed only when the sheet is used to record whole body exposures and the licensee or registrant is exposing the individual under the provisions of paragraph A.2.1 (b) which allows up to 3 rems per quarter to the whole body. Enter in this item the unused part of permissible accumulated dose taken from previous records of exposure, i.e., Item 18 of the preceding Agency Form RCA-3 or Item 13 of Agency Form RCA-2 if the individual's exposure during employment with the licensee or registrant begins with this record.

Item 7. Indicate the method used for monitoring the individual's exposure to each type of radiation to which he is exposed in the course of his duties. Abbreviations may be used.

Item 8. Doses received over a period of less than a calendar quarter need not be separately entered on the form provided that the licensee maintains a current record of the doses received by the individual which have not as yet been entered on the form. The period of exposure should specify the day the measurement of that exposure was initiated and the day on which it was terminated. For example, if only quarterly doses are entered, the period of exposure for the first calendar quarter of 1962 might be taken as running from Monday, January 1, 1962, through Friday, March 30, 1962, and would be indicated in this item as Jan. 1, 1962-Mar. 30, 1962. If weekly doses are entered, a film badge issued Monday morning, January 1, 1962, and picked up Friday, January 5, 1962, would be indicated as Jan. 1, 1962-Jan. 5, 1962.

Items 9, 10 and 11 Self-explanatory. The values are to be given in rem. All measurements are to be interpreted in the best method known and in accordance with paragraph A.1.2 (d). Where calculations are made to determine dose, a copy of such calculations is to be maintained in conjunction with this record. In any case where the dose for a calendar quarter is less than 10% of the value specified in paragraph A.2.1 (a), the phrase "less than 10%" may be entered in lieu of a numerical value.

Item 12. The running total is to be maintained on the basis of calendar quarters. Definition Number 20 defines calendar quarter. No entry need be made in this item if only calendar quarter radiation doses are recorded in Items 9, 10, 11 and 12.