

Jefferson County Department of Health Regulations to Govern the Production and Use of Radiation

TABLE OF CONTENTS

Part A General Provisions

A.1:	Authority	1
A.2:	Scope	1
A.3:	Advisory Committee	1
A.4:	Definitions	1
A.5:	Exemptions and Variances	1
A.6:	Records	2
A.7:	Inspections	2
A.8:	Test and Surveys	2
A.9:	Violations	3
A.10:	Fees	3
A.11:	Impounding	3
A.12:	Prohibited Uses	3
A.13:	Units of Radiation Dose	3
A.14:	Communications	3

Part B Registration of X-ray Producing Machines

B.1:	Purpose and Scope	5
B.2:	Registration Requirements	5
B.3:	General Definitions	5
B.4:	Exemptions	5
B.5:	Registration Procedures	5
B.6:	Issuance of Notice of Registration	7
B.7:	Expiration of Notice of Registration	7
B.8:	Renewal of Notice of Registration	7
B.9:	Report of Change	7
B.10:	Report of Discontinuance	7
B.11:	Registration Shall Not Imply Approval	7
B.12:	Assembler and/or Transfer Obligations	7
B.13:	Out of State X-ray Machines	8
B.14:	Plan Review	8
B.15:	Modification, Suspension, and Termination of Registration of Activities Registered	9

Appendices

A	Instruction of Servicers of X-ray Equipment	10
B	Information on Radiation Shielding Requested for Shielding Review	11
C	Minimum Design Requirements for an X-ray Machine Operator's Booth	12

**Part C
Standards for Protection Against Radiation**

C.1: Purpose ----- 13
 C.2: Scope ----- 13
 C.3: Definitions ----- 13
 C.4: Implementation ----- 19
 C.5: Radiation Protection Programs ----- 19

Occupational Dose Limits

C.6: Occupational Dose Limits for Adults ----- 19
 C.7: Compliance with Requirements for Sum-mation of External and Internal Dose ----- 20
 C.8: Determination of External Dose from Airborne Radioactive Materials ----- 21
 C.9: Determination of Internal Exposure ----- 21
 C.10: Determination of Prior Occupational Dose ----- 23
 C.11: Planned Special Exposures ----- 24
 C.12: Occupational Dose Limits for Minors ----- 25
 C.13: Dose to an Embryo/Fetus ----- 25

**Radiation Dose Limits for
Individual Members of the Public**

C.14: Dose Limits for Individual Members of the Public ----- 25
 C.15: Compliance with Dose Limits for Individual Members of the Public ----- 26
 C.16: Reserved

Surveys and Monitoring

C.17: General ----- 27
 C.18: Conditions Requiring Individual Monitoring of External and Internal Occupational Dose ----- 27

**Control of Exposure from
External Sources in Restricted Areas**

C.19: Control of Access to High Radiation Areas ----- 28
 C.20: Control of Access to Very High Radiation Areas ----- 29
 C.21: Reserved
 C.22: Reserved
 C.23: Reserved
 C.24: Reserved

**Storage and Control of
Registered Source of Radiation**

C.25: Security of Stored Sources of Radiation ----- 30
 C.26: Control of Sources of Radiation not in Storage ----- 30

Precautionary Procedures

C.27: Caution Signs ----- 30
 C.28: Posting Requirements ----- 30
 C.29: Exceptions to Posting Requirements ----- 31
 C.30: Labeling Containers and Radiation Machine ----- 31
 C.31: Exemptions to Labeling Requirements ----- 32

- C.32: Reserved
- C.33: Reserved
- C.34: Reserved
- C.35: Reserved
- C.36: Reserved
- C.37: Reserved
- C.38: Reserved
- C.39: Reserved

Records

- C.40: General Provisions -----32
- C.41: Records of Radiation Protection Programs-----32
- C.42: Records and Surveys -----33
- C.43: Reserved
- C.44: Records of Prior Occupational Dose -----33
- C.45: Records of Planned Special Exposures-----33
- C.46: Records of Individual Monitoring Results -----34
- C.47: Records of Dose to individual Members of the Public -----35
- C.48: Reserved
- C.49: Records of testing Entry Control Devices for Very High Radiation Areas-----35
- C.50: Form of Records -----35

Reports

- C.51: Reports of Stolen, Lost, or Missing Registered Sources of Radiation -----35
- C.52: Notification of Incidents-----36
- C.53: Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material
Exceeding the Limits -----37
- C.54: Reports of Planned Special Exposures-----38
- C.55: Reserved
- C.56: Reports of Individual Monitoring-----38
- C.57: Notifications and Reports to Individuals -----38

Part D

Radiation Safety Requirements for Industrial Radiographic Operations

- D.1: Purpose-----41
- D.2: Scope -----41
- D.3: Definitions-----41
- D.4: Locking of Sources of Radiation-----41
- D.5: Radiation Survey Instruments-----41
- D.6: Quarterly Inventory -----41
- D.7: Utilization Logs -----42

Personal Radiation Safety Requirements for Radiographers and Radiographers Assistants

- D.8: Limitations -----42
- D.9: Operating and Emergency Procedures-----43
- D.10: Personnel Monitoring Control -----43
- D.11: Supervision of Radiographer’s Assistant-----43

Precautionary Procedures in Radiographic Operations

D.12: Security-----44
 D.13: Posting -----44
 D.14: Radiation Surveys and Survey Records -----44
 D.15: Special Requirements and Exemptions-----44

Appendices

A Instruction of Radiographers-----46

Part E
Radiation Safety Requirements for Users of X-rays in Healing Arts or
Servicers of X-ray Equipment

Section

E.1: Scope-----47
 E.2: Definitions -----47
 E.3: General Requirements -----47
 E.4: General Requirements for All Diagnostic X-ray Equipment -----51
 E.5: Fluoroscopic X-ray Equipment -----53
 E.6: Radiographic Installations Other than Fluoroscopic, Intraoral Dental, and Veterinary
 Medicine -----58
 E.7: Reserved-----64
 E.8: Intraoral Dental Radiographic Installation Systems -----64
 E.9: Therapeutic X-ray Systems -----67
 E.10: X-ray Therapy Equipment Operated at Potentials of Sixty (60) kV and Below -----68
 E.11: Veterinary Medicine Radiographic Installations-----69

Appendices

A Request for the Use of X-rays for Healing Arts Screening -----71

Part F
Notices, Instructions and Reports to Workers

Section

F.1: Purpose and Scope-----73
 F.2: Posting of Notices to Workers -----73
 F.3: Instructions to Workers-----74
 F.4: Notification and Reports to Workers -----74

Part G
Inspections

Section

G.1: Presence of Representatives of Registrants and Workers During Inspections -----77
 G.2: Consultations with Workers During Inspections-----77
 G.3: Request by Workers for Inspections -----78
 G.4: Inspections Not Warranted; Informal Review -----78

**Part H
Radiation Safety Requirements for Analytical X-ray Equipment**

Section

H.1:	Purpose and Scope -----	79
H.2:	Definitions-----	79
H.3:	Equipment Requirements-----	79
H.4:	Area Requirements-----	80
H.5:	Operating Requirements-----	81
H.6:	Personnel Requirements-----	81

**Part I
Tanning Facilities**

Section

I.1:	Authority, Purpose and Scope -----	83
I.2:	Definitions-----	83
I.3:	Exemptions-----	84
I.4:	Application for Permitting of Tanning Facilities-----	84
I.5:	Issuance of Permit-----	85
I.6:	Expiration of Permit-----	85
I.7:	Renewal of Permit-----	85
I.8:	Report of Change-----	85
I.9:	Transfer of Permit-----	85
I.10:	Approval Not Implied-----	85
I.11:	Denial, Suspension, or Revocation of Permit-----	85
I.12:	Construction and Operation of Tanning Facilities-----	86
I.13:	Enforcement and Penalties-----	89
I.14:	Inspections-----	89
I.15:	Severability-----	89
I.16:	Effective Date-----	89

Appendices

A	Warning Sign-----	90
B	Minimum Design Requirements for a Tanning Device Room-----	91
C	Report of Injury Form-----	92

Glossary -----	93
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PART A
GENERAL PROVISIONS

Section A.1: Authority.

The Jefferson County Board of Health is authorized to promulgate these regulations under and by virtue of the authority of **Chapter 3, Title 22-3-2, Title 22-14-2 through 14-15 (Code of Alabama 1975); and Act No. 582, Alabama Legislature, Regular Session 1963.**

Section A.2: Scope.

Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own, or acquire any machine produced source of radiation; provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the State of Alabama rules relating to particle accelerators. The provisions of **Part C** of these regulations shall not be interpreted as limiting the intentional exposure of patients to radiation for the purpose of diagnosis or therapy by persons licensed to practice one or more of the healing arts within the authority granted to them by Alabama healing arts statutes, or persons licensed to practice dentistry or podiatry within the authority granted to them by Alabama licensing laws applying to dentists and podiatrists.

Section A.3: Advisory Committee.

A Radiological Health Advisory Committee may be appointed by the Health Officer with approval of the Jefferson County Board of Health to advise the Department through its Bureau of Environmental Health on matters assigned to it pertaining to radiation protection and the development of necessary regulations.

Section A.4: Definitions.

Definitions as used in this Part are found in the Glossary.

Section A.5: Exemptions and Variances.

- (a) **General Provisions.** The Department may, upon application therefor or upon its own initiative, grant such exemptions from or exceptions to 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) The Health Officer may accept as a variance substitute procedures or controls in lieu of the specific design or installation requirements of these regulations provided the conditions of such a variance will provide protection equivalent to that required herein. Such variances shall not be effective until the specific conditions thereof are approved in writing by the Health Officer.
- (c) **U.S. Department of Energy and U.S. Nuclear Regulatory Commission Contractors.** Any **U.S. Department of Energy** contractor or subcontractor and any **U.S. Nuclear Regulatory Commission** contractor or subcontractor of the following categories operating within this County are exempt from these regulations to the extent that such contractors or subcontractors under their contracts receive, possess, use, transfer, own, or acquire sources of radiation:
 - (1) Prime contractors performing work for the **U.S. Department of Energy** at U.S.

Government-owned or controlled sites;

- (2) Prime contractors performing research in or development, manufacture, storage, testing, or transportation of atomic weapons or components thereof;
- (3) Prime contractors using or operating nuclear reactors or other nuclear devices in U.S. Government-owned vehicles or vessels; and
- (4) Any other prime contractor or subcontractor when the County and the **U.S. Nuclear Regulatory Commission** jointly determine that:
 - (i) 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 or property; and
 - (ii) The exemption of such contractor or subcontractor is otherwise appropriate.

Section A.6: Records.

Each registrant shall maintain records showing the receipt, transfer, and/or disposal of all sources of radiation and any other records as specifically required by these regulations.

- (a) Records of receipt shall be maintained until two years after transfer and/or disposal.
- (b) Records of transfer shall be maintained until five years after transfer.
- (c) Records of disposal shall be maintained until the Department authorizes their disposition.

Section A.7: Inspections.

- (a) Each registrant shall afford, at all reasonable times, the Department the opportunity to inspect sources of radiation and the premises of the installation wherein the sources of radiation are used and/or stored.
- (b) Each registrant shall make available to the Department for inspection, upon reasonable notice, records maintained pursuant to these regulations.
- (c) The Department may immediately impound or order the impounding of sources of radiation in the possession of any person who is not equipped to observe or fails to observe these regulations or provisions of the Act.

Section A.8: Test and Surveys.

- (a) Each registrant shall make or cause to be made such surveys as are necessary for him to comply with these regulations.
- (b) Each registrant shall perform, upon the instruction of the Department, or shall permit the Department to perform such reasonable tests as the Department deems to be appropriate or necessary including, but not limited to, tests of:
 - (1) Sources of radiation;
 - (2) Installations wherein sources of radiation are used and stored;
 - (3) Radiation detection and monitoring instruments; and
 - (4) Other equipment and devices used in connection with utilization or storage of sources of radiation.

Section A.9: Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of these regulations or any order issued thereunder.

Section A.10: Fees.

- (a) This Department is authorized under the provisions of **Section 1 paragraph (i) of Act No. 88-895, Alabama Legislature, Regular Session 1988** to collect fees for inspection and certification services performed in connection with the administration and enforcement of public health and environmental laws and regulations.
- (b) The Department may immediately suspend or terminate the registration/permit of sources of radiation, as defined in these regulations, in the possession of any person who fails to pay fees authorized under **Section A.10(a)**.

Section A.11: Impounding.

Sources of radiation shall be subject to impounding pursuant to **Section 15 of the Act**.

Section A.12: Prohibited Uses.

- (a) It shall be unlawful to operate any device or machine using fluoroscopic x-rays or ionizing radiation principles for the fitting or selling of footwear.
- (b) It shall be unlawful to intentionally apply ionizing radiation to human beings except by or under direct supervision of persons licensed to practice healing arts and authorized to use such radiation or as otherwise provided in these regulations related to exposure.
- (c) It shall be unlawful for any person to use, receive, or possess any source of radiation unless the source of radiation is registered or exempted by the Department and is operated in compliance with all applicable provisions of these regulations.
- (d) Hand-held or hand-type fluoroscopes are prohibited and shall not be used.

Section A.13: Units of Radiation Dose.

- (a) **Dose.** Dose is the quantity of radiation absorbed, per unit mass, by the body or any portion of the body. When these regulations specify a unit of dose during a period of time, dose means the total quantity of radiation absorbed, per unit mass, by the body or any portion of the body during such period of time. Several different units of dose are in current use. Definitions of units of dose as used in these regulations are set forth in the Glossary under the terms "rem" and "rad."
- (b) The "roentgen" is a unit of exposure and is defined as used in these regulations in the Glossary.
- (c) For determining exposure to x- or gamma rays up to 3 MeV, the dose limits specified in **Part C** may be assumed to be equivalent to the "air dose" (see Glossary for definition).

Section A.14: Communications.

All communications and reports concerning these regulations or required by these regulations shall be addressed to:

**Jefferson County Department of Health
Bureau of Environmental Health
1400 6th Avenue South
P.O. Box 2648
Birmingham, Alabama 35202-2648**

Attention: Division of Radiological Health

Author: James D. Archer, Jr., Environmental Health Program Supervisor.

Authority: §§; 22-2-1, 22-2-2, 22-2-5, and 22-2-6; and 22-3-4; also 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, Code of Alabama, 1975.

History: Promulgated Jan. 1, 1961; revised Sept. 1, 1969; Nov. 1, 1971; revised Oct. 1, 1977; revised June 10, 1981; revised Aug. 12, 1986; revised NOV. 9, 1994

PART B

REGISTRATION OF X-RAY PRODUCING MACHINES

Section B.1: Purpose and Scope.

- (a) This Part provides for the registration of x-ray producing machine facilities and for the registration of persons providing x-ray producing machine installation, servicing, and/or services.
- (b) In addition to the requirements of this Part, all registrants are subject to the applicable provisions of other Parts of these regulations.

Section B.2: Registration Requirements.

Every person possessing an x-ray producing machine capable of producing x-rays of less than 0.9 MeV shall register in accordance with the provisions of these regulations.

Section B.3: General Definitions.

Definitions as used in this Part are found in the Glossary.

Section B.4: Exemptions.

The following materials and devices do not require registration:

- (a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Part, provided dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem per hour at 5 centimeters from any accessible surface of such equipment.
- (b) X-ray producing machines while in transit or storage incident thereto are exempt from the requirements of this Part.
- (c) All radioactive materials are exempt from the requirements of this Part.
- (d) Domestic television receivers are exempt from this Part.

Section B.5: Registration Procedures.

- (a) **Initial Registration of X-ray Producing Machines.** Every person who possesses an x-ray producing machine shall register the machine with the Department by June 1, 1965, on application forms prescribed by the Department. Every person not already registered who acquires possession of an x-ray producing machine subsequent to June 1, 1965, shall register with the Department prior to acquiring an x-ray machine.

In addition such person shall:

- (1) Designate on the application form an individual responsible for radiation protection;
- (2) Prohibit any person from furnishing x-ray producing machine servicing or services, as described in **Section B.5(b)(3)**, to his/her x-ray producing machine facility until such person provides evidence that he is registered with the Department as a provider of services in accordance with **Section B.5(b)**.

- (b) **Registration of Services.** Every person who is engaged in the business of installing or offering to install x-ray producing machines or is engaged in the business of furnishing or offering to furnish x-ray producing machine servicing or services in this County shall apply for the registration of such services with the Department by October 1, 1974, on application forms prescribed by the Department. Every person not already registered who plans to furnish or offer to furnish x-ray producing machine servicing or services subsequent to October 1, 1974, shall apply for registration with the Department thirty (30) days prior to furnishing or offering to furnish any such services.
- (1) Applications for registration shall be completed on forms provided by the Department and shall contain all information required by the Department as indicated on the forms and accompanying instructions.
 - (2) Each person applying for registration under this Part shall specify:
 - (i) That he/she has read and understands the requirements of these regulations;
 - (ii) The services for which he/she is applying for registration;
 - (iii) The training and experience that qualify him/her to discharge the services for which he is applying for registration;
 - (iv) The type of radiation measurement instrument to be used, frequency of calibration, and source of calibration; and
 - (v) The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.
 - (3) For the purpose of **Section B.5**, services may include, but shall not be limited to:
 - (I) Installation and/or servicing of x-ray producing machines and associated x-ray producing machine components;
 - (ii) Calibration of x-ray producing machines or radiation measurement instruments or devices used in calibrating x-ray producing machines;
 - (iii) Radiation protection or health physics consultations or surveys; and
 - (iv) Personnel dosimetry services.
 - (4) No registrant shall permit any individual to perform services until such person:
 - (i) Has been instructed in the subjects outlined in **APPENDIX A** to this Part, and shall have demonstrated understanding thereof;
 - (ii) Has received copies of and instruction in the regulations contained in this Part and the applicable **Sections** of **Parts C** and **F** and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;
 - (iii) Has demonstrated competence to use the source of ionizing radiation and survey instruments which will be employed in his assignment; and
 - (iv) Has demonstrated understanding of the instructions in this paragraph by successfully completing a written or oral test and a field examination of the subjects covered.
 - (5) No individual shall perform services which are not specifically stated for that individual in

the notice of registration issued by the Department.

Section B.6: Issuance of Notice of Registration.

- (a) Upon a determination by the Department that an applicant meets the requirements of the regulations, the Department shall issue a notice of registration.
- (b) The Department may incorporate in the notice of registration, at the time of issuance or thereafter by appropriate regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, or transfer of x-ray producing machines as it deems appropriate or necessary.

Section B.7: Expiration of Notice of Registration.

Except as specifically provided by **Section B.8(b)**, each notice of registration shall expire at the end of the specified day in the month and year stated therein.

Section B.8: Renewal of Notice of Registration.

- (a) Applications for renewal of registration shall be filed in accordance with **Section B.5**.
- (b) In any case in which a registrant not less than thirty (30) days prior to the expiration of his existing notice of registration has filed an application in proper form for renewal, such existing notice shall not expire until the application status has been finally determined by the Department.

Section B.9: Report of Change.

Within thirty (30) days of change, the registrant shall notify the Department in writing before making any change which would render the information contained in the application for registration and/or the notice of registration no longer accurate.

Section B.10: Report of Discontinuance.

Every registrant who permanently discontinues the use of or permanently disposes of all his x-ray producing machines at an installation shall notify the Department within thirty (30) days prior to such action.

Section B.11: Registration Shall Not Imply Approval.

No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Department pursuant to the provisions of **Section B.4** or **B.5**, and no person shall state or imply that any activity so registered has been approved by the Department.

Section B.12: Assembler and/or Transfer Obligations.

- (a) Any person who sells, leases, installs, transfers, or lends x-ray producing machines in this County shall notify the Department within thirty (30) days after the end of each calendar quarter of:
 - (1) The following information:
 - (i) The name and address of persons who have received these machines;
 - (ii) The manufacturer, model and serial numbers, and date of manufacture of each machine; and

- (iii) The date of transfer of each x-ray producing machine.
- (2) **Negative Reports.** Such reports shall be furnished to the Department within thirty (30) days after the end of the calendar quarter.
- (b) The requirement of **Section B.12(a)** shall be deemed fulfilled if a similar report is filed with the Alabama State Department of Health and a copy of said report is subsequently made available to the Jefferson County Department of Health.
- (c) No person shall make, sell, lease, transfer, or install x-ray equipment or the accessories used in connection with such equipment unless such accessories and equipment, when properly placed in operation and properly used, will meet the requirements of these regulations. This includes the responsibility for the delivery of cones or collimators, filters, adequate timers, and fluoroscopic shutters. Further, no person shall sell, lease, deliver, install, or place in operation any x-ray equipment at any facility or for any person not registered with the Department.

Section B.13: Out-of State X-ray Machines.

- (a) Whenever any x-ray producing machine is brought into the County for any temporary use, the person proposing to bring such machine into the County shall give written notice to the Department at least two (2) days before such machine enters the County. The notice shall include:
 - (1) The type of x-ray machine;
 - (2) The nature, duration, and scope of it's use; and
 - (3) The exact location where the x-ray machine is to be used.
- (b) If for a specific case the two (2) day period would impose an undue hardship on the person, he may upon application to the Department obtain permission to proceed sooner.
- (c) The person referred to in **Section B.13(a)** shall:
 - (1) Comply with all applicable regulations of the Department; and
 - (2) Supply the Department with such other information as the Department may reasonably request.

Section B.14: Plan Review.

- (a) Prior to construction, the floor plans and equipment arrangement of all installations (new or modification of existing installations) utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the Department for review and approval. An outline of the required information is set forth **APPENDICES B** and **C** to this Part.
- (b) The Department may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to review and approval.
- (c) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual's receiving a dose in excess of the limits prescribed in **Part C**.

Section B.15: Modification, Suspension, and Termination of a Registration of Activities Registered.

- (a) A registration or activity registered shall be subject to amendment, revision, or modification; or such activity may be suspended or terminated by reason of amendment of the Act, or by reason of rules, regulations and orders issued by the Department.
- (b) Any registration or activity registered may be terminated, suspended, or modified in whole or part for any material false statement in the application, or because of conditions revealed by such application, or statement of fact; or any report, record, inspection, or other means which would warrant the Department to refuse to grant a registration on an original application; or for violation of or failure to observe any of the terms or conditions of the Act, or any regulations or orders of the Department.
- (c) Except in the cases of willfulness, or those in which the public health interest or safety requires otherwise, no registration or activity registered shall be modified, suspended, or terminated unless, prior to institution of proceedings thereof, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been afforded an opportunity to demonstrate or achieve compliance with all lawful requirements.

Author: James D. Archer, Jr., Environmental Health Program Supervisor.

Authority: §§; 22-2-1, 22-2-2, 22-2-5, and 22-2-6; and 22-3-4; also 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, Code of Alabama, 1975.

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APPENDIX A

INSTRUCTION OF SERVICERS OF X-RAY EQUIPMENT

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 Distance.
 - 3. Shielding.

II. Radiation Detection Instrumentation to be Used.

- A. Use of Radiation Survey Instruments:
 - 1. Operations.
 - 2. Calibration.
 - 3. Limitations.
- B. Survey Techniques.
- C. Use of Personnel Monitoring Equipment:
 - 1. Film Badges and/or Thermoluminescence Dosimeters (TLD's).
 - 2. Pocket dosimeters.
 - 3. Pocket Chambers.

III. Operation and Control of X-ray Equipment.

- A. Effects of Collimation and Filtration.
- B. Film Processing Techniques.

IV. The Requirements of Pertinent Federal, State, and Local Regulations.

APPENDIX B**INFORMATION ON RADIATION SHIELDING REQUESTED FOR PLAN REVIEW**

In order for the Department to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information is required:

- A. **Plans.** At least two sets of plans (to scale) should be submitted. The plans should show, as a minimum, the following:
- (1) (i) Normal location of the x-ray producing equipment's radiation ports and the port's travel and transverse limits; (ii) General direction(s) of the radiation beam; (iii) Locations of any window(s); (iv) Location of the operator's booth; and (v) Location of the equipment's control console;
 - (2) Structural composition and thicknesses of all walls, doors, partitions, floor and ceiling of the room(s) concerned;
 - (3) Height (floor to floor) of the room(s) concerned;
 - (4) 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 existing occupied area(s);
 - (5) Make and model of the x-ray producing equipment including the maximum energy output (for x-ray machines this is the kilovolt peak potential) and maximum mA; and
 - (6) The type of examination(s) or treatment(s) which will be performed with the equipment (e.g., dental orthodontal, chest, gastrointestinal, fluoroscopic, podiatry, fixed therapy, rotational therapy, etc...).
- B. **Anticipated Workload.** Information on the anticipated workload used in shielding calculations shall be provided by the registrant (i.e., mA, kVp, time, and expected number of x-rays per week).
- C. If the services of a qualified radiation expert have been utilized, a copy of his report shall be submitted with the plans. This report shall show all basic assumptions (i.e., workload, occupancy and use factors, distances, etc...) used to determine the shielding requirements.

APPENDIX C

MINIMUM DESIGN REQUIREMENTS FOR AN X-RAY MACHINE OPERATOR'S BOOTH

The operator's station at the control panel shall be behind a protective barrier either in a separate room, a protected booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.

- A. **Space.** Not less than 7.5 square feet of unobstructed floor space shall be allotted to the operator. This space shall be allotted excluding any encumbrance by the console, such as overhangs and cables or similar encroachments. It may be any geometric configuration with no dimension of less than two (2) feet.
- B. **Walls.** The booth walls shall be at least seven (7) feet high and shall be permanently fixed to the floor or other structure as may be necessary.
- C. **Door or Moveable Panel.** When a door or moveable panel is used as an integral part of the booth structure, it must have a permissive device which will prevent an exposure when the door or panel is not closed (this type of booth structure is not recommended).
- D. **Switch.** The exposure switch shall be fixed within the booth at least thirty (30) inches from any open edge of the booth wall which is proximal to the examining table, and shall allow the operator to use the majority of the available viewing window.
- E. **Viewing System.** Each booth shall have at least one viewing device which shall be so placed that the operator can view the patient, have full view of any occupant of the room, and view any entry to the room during any exposure. If any door which allows access into the room cannot be seen from the booth, then that door must have a permissive device controlling the exposure switch which prevents an exposure when the door is not closed.
 - (1) When the viewing system is a window:
 - (i) It shall have a visible area of at least one (1) square foot and be so positioned that some portion of it is five (5) feet above the floor;
 - (ii) The distance between its proximal edge and the open edge of the booth shall not be less than thirteen (13) inches; and
 - (iii) The glass shall have the same lead equivalence as that required in the booth's walls in which it is to be mounted.
 - (2) When the viewing system is by mirrors, they shall be so located as to accomplish the general requirements as in paragraph E.
 - (3) When the viewing system is by electronic means (e.g., TV, etc...), the camera shall be so located as to accomplish the general requirements as in paragraph E.

There shall be an alternative viewing system as a backup for electronic failure.

PART C
STANDARDS FOR PROTECTION AGAINST RADIATION
GENERAL PROVISIONS

Section C.1 Purpose.

- (a) This Part establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to registrations issued by the Department. These Regulations are issued pursuant to **Act No. 582, Regular Session, 1963, as amended**.
- (b) The requirements of this Part are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this Part. However, nothing in this Part shall be construed as limiting actions that may be necessary to protect health and safety.

Section C.2 Scope.

- (a) Except as specifically provided in other parts of these Regulations, this Part applies to persons registered by the Department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this Part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

Section C.3 Definitions. As used in this Part:

Absorbed dose - means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

Activity - is the rate of disintegration (transformation) or decay of radioactive material. The units of Activity are the curie (Ci) and the becquerel (Bq).

Adult - means an individual 18 or more years of age.

Airborne radioactive material - means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Airborne radioactivity area - means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of registered material, exist in concentrations: (1) In excess of the derived air concentrations (DACs) specified in **Appendix B¹, Table I**. (2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours the individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

As low as is reasonably achievable (ALARA) - means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics

¹ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and registered sources of radiation in the public interests.

Annual limit on intake (ALI) - means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in **Table I, Columns 1 and 2, of Appendix B.**²

Background radiation - means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Department.

Bioassay - means the determination of kinds, quantities or concentrations, and, in some cases, quantities of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.

Class - means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

Collective dose - is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Committed dose equivalent ($H_T,50$) - means the dose equivalent to organs or tissues of reference (t) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Committed effective dose equivalent ($H_E,50$) - is the sum of the products of the weighting factors applicable to each of the body organs that are irradiated and the committed dose equivalent to these organs or tissues ($H_E,50 = \sum w_T h_T,50$).

Controlled area - means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the registrant for any reason.

Declared pregnant woman - means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

Deep-dose equivalent (H_d) - which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm. (1000 mg/cm^2).

Derived air concentration (DAC) - means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are

² Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

given in **Table I, Column 3**, of **Appendix B**.³

Derived air concentration-hour (DAC-hour) - means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

Dosimetry processor - means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

Effective dose equivalent (H_E) - is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = W_T H_T$).

Embryo/fetus - means the developing human organism from conception until the time of birth.

Entrance or access point - means any location through which an individual could gain access to radiation areas or to radioactive materials or machines which produce radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Exposure - means being exposed to ionizing radiation or to radioactive material.

External dose - means that portion of the dose equivalent received from radiation sources outside the body.

Extremity - means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

Eye dose equivalent - applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).

High radiation area - means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Individual - means any human being.

Individual monitoring - means: (1) The assessment of dose equivalent by the use of devices designed to be worn by an individual; (2) The assessment of committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or (3) The assessment of dose equivalent by the use of survey data.

Individual monitoring devices - means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

Inhalation class - see "Class".

Internal dose - means that portion of the dose equivalent received from radioactive material

³ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

taken into the body.

License - means a license issued by the Department in accordance with the regulations adopted by the Department.

Licensed material - means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Department.

Limits (dose limits) - means the permissible upper bounds of radiation doses.

Lost or missing registered source of radiation - means registered source of radiation whose location is unknown. This definition includes registered source that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

Member of the public - means an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

Minor - means an individual less than 18 years of age.

Monitoring - means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

Nonstochastic effect - means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

Occupational dose - means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the registrant, or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

Person - means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Department, political subdivision of this State, any other State or political subdivisions or Department thereof, and any legal successor, representative, agent, or Department of the foregoing other than the **U.S. Nuclear Regulatory Commission**, and other Federal Government Agencies licensed by the **U.S. Department of Energy**, and other than Federal Government Agencies licensed by the **U.S. Nuclear Regulatory Commission**.

Planned special exposure - means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

Public dose - means the dose received by a member of the public from exposure to sources of radiation either within a registrant's controlled area or in unrestricted areas. It does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices, or dose from voluntary participation in medical research programs.

Quality factor (Q) - means the modifying factor listed in the table below that is used to derive dose equivalent from absorbed dose:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent ^a
X, gamma, or beta radiation and high-speed electrons	1	
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

^a Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

Quarter - means a period of time equal to one-fourth of the year observed by the registrant, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Radiation - means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

Radiation area - means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (5 millirem) (0.05 mSv) in one hour at 30 centimeters from the radiation source or from the surface that the radiation penetrates.

Reference Man - means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

Respiratory protective equipment - means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

Sanitary sewerage - means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the registrant.

Shallow-dose equivalent (H_s) - which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm²) averaged over an area of one square centimeter.

Site boundary - means that line beyond which the land or property is not owned, leased, or otherwise controlled by the registrant.

Stochastic effect - means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.

Survey - means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive materials present.

Total effective dose equivalent (T_{EDE}) - means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Unrestricted area - access to which is neither limited nor controlled by the registrant.

Very high radiation area - means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rad (5 Grays) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates.¹

Week - means 7 consecutive days starting on Sunday.

Weighting factor (W_T) - for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

ORGAN OR TISSUE	W_T
Gonads	.25
Breast	.15
Red Bone Marrow	.12
Lung	.12
Thyroid	.03
Remainder	.03 ^a
Whole Body	1.00 ^b

a 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

b For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued

Whole body - means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

Working level (WL) - is any combination of short lived radon daughters in one liter of air that will result in the ultimate emission of $1.3E+5$ MeV of potential alpha particle energy. The short-lived radon daughters are for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, bismuth-212, and polonium-212.

Working level month (WLM) - means an exposure to 1 working level for 170 hours (2,000

working hours per year/12 months per year equals approximately 170 hours per month).

Year - means the period of time beginning in January used to determine compliance with the provisions of these regulations. The registrant may change the starting date of the year used to determine compliance by the registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

Section C.4 Implementation.

- (a) Any existing registration condition that is more restrictive than this Part remains in force until there is an amendment or renewal of the registration.
- (b) If a registration condition exempts a registrant from a provision of this Part in effect on or before January 1, 1994, it also exempts the registrant from the corresponding provision of this Part.
- (c) If a registration condition cites provisions of this Part in effect prior to January 1, 1994, which do not correspond to any provisions of this Part, the registration condition remains in force until there is an amendment or renewal of the registration that modifies or removes this condition.

RADIATION PROTECTION PROGRAMS

Section C.5 Radiation Protection Programs.

- (a) Each registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this Part. See **Section C.41** for record keeping requirements relating to these programs.
- (b) The registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (**ALARA**).
- (c) The registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

OCCUPATIONAL DOSE LIMITS

Section C.6 Occupational Dose Limits for Adults.

- (a) The registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to **Section C.11**, to the following dose limits:
 - (1) An annual limit, which is the more limiting of:
 - (i) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or
 - (ii) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).
 - (2) The annual limits to the lens of the eye, to the skin, and to the extremities which are:
 - (i) An eye dose equivalent of 0.15 Sv (15 rem), and

- (ii) A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.
- (b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See **Section C.11(e)(1)**.
- (c) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:
 - (1) The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or
 - (2) When a protective apron is worn and monitoring is conducted as specified in **Section C.18(c)**, the effective dose equivalent for external radiation shall be determined as follows:
 - (i) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in **Section C.6(a)**, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or
 - (ii) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.
- (d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in **Table I of Appendix B**⁴ and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See **Section C.46**.
- (e) Notwithstanding the annual dose limits, the registrant shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See **footnote 3 of Appendix B**.⁵
- (f) The registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See **Section C.10(e)**.

Section C.7 Compliance with Requirements for Summation of External and Internal Doses.

- (a) If the registrant is required to monitor pursuant to both **Section C.18(a)** and **(b)**, the registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the registrant is required to monitor only pursuant to **Section C.18(a)** or only pursuant to **Section C.18(b)**, then summation is not required to demonstrate compliance with the dose

⁴ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

⁵ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

limits. The registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to **Section C.7(b), (c), and (d)**. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

- (b) **Intake by Inhalation.** If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:
- (1) The sum of the fractions of the inhalation ALI for each radionuclide, or
 - (2) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or
 - (3) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factor, W_T , and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50} (i.e. $W_T H_{T,50}$, per unit intake for any organ or tissue).
- (c) **Intake by Oral Ingestion.** If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the registrant shall account for this intake and include it is demonstrating compliance with the limits.
- (d) **Intake through wounds or Absorption through Skin.** The registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to **Section C.7(d)**.

Section C.8 Determination of External Dose from Airborne Radioactive Material.

- (a) Registrant shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. **See Appendix B, footnotes 1 and 2.**⁶
- (b) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

Section C.9 Determination of Internal Exposure.

- (a) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the registrant shall, when required pursuant to **Section C.18**, take suitable and timely measurements of:
- (1) Concentrations of radioactive materials in air in work areas; or

⁶ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

- (2) Quantities of radionuclides in the body; or
 - (3) Quantities of radionuclides excreted from the body; or
 - (4) Combinations of these measurements.
- (b) Unless respiratory protective equipment is used, as provided in **Section C.24**, or the assessment of intake is based on bioassays, the registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.
- (c) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the registrant may:
- (1) Use that information to calculate the committed effective dose equivalent, and, if used, the registrant shall document that information in the individual's record; and
 - (2) Upon prior approval of the Department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and
 - (3) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. **See Appendix B.**⁷
- (d) If the registrant chooses to assess intakes of Class Y material using the measurements given in **Section C.9(a)(2)** and **(3)**, the registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by **Section C.52** or **Section C.53**. This delay permits the registrant to make additional measurements basic to the assessments.
- (e) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:
- (1) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from **Appendix B**⁸ for each radionuclide in the mixture; or
 - (2) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.
- (f) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.
- (g) When a mixture of radionuclides in air exists, a registrant may disregard certain radionuclides in the mixture if:
- (1) The registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in **Section C.6** and in complying with the monitoring requirements in **Section C.17(b)** and **(c)**, and
 - (2) The concentration of any radionuclide disregarded is less than 10 percent of its DAC,

⁷ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

⁸ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

and

- (3) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.
- (h) When determining the committed effective dose equivalent, the following information may be considered:
- (1) In order to calculate the committed effective dose equivalent, the registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
 - (2) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in **Table I of Appendix B.**⁹ The registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the registrant uses the stochastic ALI, the registrant shall also demonstrate that the limit in **Section C.6(a)(1)(i)** is met.

Section C.10 Determination of Prior Occupational Dose.

- (a) For each individual who may enter the registrant's restricted or controlled area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to **Section C.18**, the registrant shall:
- (1) Determine the occupational radiation dose received during the current year; and
 - (2) Attempt to obtain the records of lifetime cumulative occupational radiation dose.
- (b) Prior to permitting an individual to participate in a planned special exposure, the registrant shall determine:
- (1) The internal and external doses from all previous planned special exposures; and
 - (2) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and
 - (3) All lifetime cumulative occupational radiation dose.
- (c) In complying with the requirements of **Section C.10(a)**, a registrant may:
- (1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and
 - (2) Accept, as the record of lifetime cumulative radiation dose, an up-to-date Department Form Y or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant; and

⁹ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

- (3) Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant, by telephone, telegram, facsimile, or letter. The registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.
- (d) (1) The registrant shall record the exposure history as required by **Section C.10(a)**, on Department Form Y, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the registrant obtains reports, the registrant shall use the dose shown in the report in preparing Department Form Y or equivalent. For any period in which the registrant does not obtain a report, the registrant shall place a notation on Department Form Y or equivalent indicating the periods of time for which data are not available.
 - (2) Registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the regulations in this Part in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on Department Form Y or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.
 - (e) If the registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the registrant shall assume:
 - (1) In establishing administrative controls pursuant to **Section C.6(f)** for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and,
 - (2) That the individual is not available for planned special exposures.
 - (f) The registrant shall retain the records on Department Form Y or equivalent until the Department terminates each pertinent registration requiring this record. The registrant shall retain records used in preparing Department Form Y or equivalent for 3 years after the record is made.

Section C.11 Planned Special Exposures.

A registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in **Section C.6** provided that each of the following conditions is satisfied:

- (a) The registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.
- (b) The registrant, and employer if the employer is not the registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.
- (c) Before a planned special exposure, the registrant ensures that each individual involved is:
 - (1) Informed of the purpose of the planned operation; and
 - (2) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

- (3) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.
- (d) Prior to permitting an individual to participate in a planned special exposure, the registrant ascertains prior doses as required by **Section C.6(b)** during the lifetime of the individual for each individual involved.
- (e) Subject to **Section C.6(b)**, the registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:
 - (1) The numerical values of any of the dose limits in **Section C.6(a)** in any year; and
 - (2) Five times the annual dose limits in **Section C.6(a)** during the individual's lifetime.
- (f) The registrant maintains records of the conduct of a planned special exposure in accordance with **Section C.45** and submits a written report in accordance with **Section C.54**.
- (g) The registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to **Section C.6(a)** but shall be included in evaluations required by **Section C.11(d)** and **(e)**.

Section C.12 Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in **Section C.6**.

Section C.13 Dose to an Embryo/Fetus.

- (a) The registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See **Section C.46** for record keeping requirements.
- (b) The registrant shall make efforts to avoid substantial variation* above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in **Section C.13(a)**.
- (c) The dose to an embryo/fetus shall be taken as the sum of:
 - (1) The deep dose equivalent to the declared pregnant woman; and
 - (2) The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.
- (d) If by the time the woman declares pregnancy to the registrant, the dose to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the registrant shall be deemed to be in compliance with **Section C.13(a)** if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

Section C.14 Dose Limits for Individual Members of the Public.

- (a) Each registrant shall conduct operations so that:
- (1) The total effective dose equivalent to individual members of the public from the registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from the registrant's disposal of radioactive material into sanitary sewerage in accordance with **Section C.35,**** and
 - (2) The dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour.
- (b) If the registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.
- (c) A registrant, or an applicant for a registration may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem). This application shall include the following information:
- (1) Demonstration of the need for an the expected duration of operations in excess of the limit in **Section C.14(a)**; and
 - (2) The registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit; and
 - (3) The procedures to be followed to maintain the dose ALARA.
- (d) In addition to the requirements of this Part, a registrant subject to the provisions of the **U.S. Environmental Protection Department's** generally applicable environmental radiation standards in **40 CFR 190** shall comply with those standards.
- (e) The Department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a registrant may release in effluents in order to restrict the collective dose.

Section C.15 Compliance with Dose Limits for Individual Members of the Public.

- (a) The registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in **Section C.14**.
- (b) A registrant shall show compliance with the annual dose limit in **Section C.14** by:
- (1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the registered operation does not exceed the annual dose limit; or
 - (2) Demonstrating that:
 - (i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the

values specified in **Table II** of **Appendix B**¹⁰; and

- (ii) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.
- (c) Upon approval from the Department, the registrant may adjust the effluent concentration values in **Appendix B**¹¹, **Table II**, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

SURVEYS AND MONITORING

Section C.17 General.

- (a) Each registrant shall make, or cause to be made, surveys that:
 - (1) Are necessary for the registrant to comply with this Part; and
 - (2) Are necessary under the circumstances to evaluate:
 - (i) Radiation levels; and
 - (ii) Concentrations or quantities of radioactive material; and
 - (iii) The potential radiological hazards that could be present.
- (b) The registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured.
- (c) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by registrants to comply with **Section C.6**, with other applicable provisions of these, or with conditions specified in a registration shall be processed and evaluated by a dosimetry processor:
 - (1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and
 - (2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
- (d) The registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

Section C.18 Conditions Requiring Individual Monitoring of External and Internal

¹⁰ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

¹¹ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

Occupational Dose.

Each registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this Part. As a minimum:

- (a) Each registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:
 - (1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in **Section C.6(a)**; and
 - (2) Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in **Section C.12** or **Section C.13**; and
 - (3) Individuals entering a high or very high radiation area.
 - (4) **Reserved.**
- (b) Each registrant shall monitor, to determine compliance with **Section C.9**, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
 - (1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in **Table I, Columns 1 and 2, of Appendix B**¹²; and
 - (2) Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).
- (c) For individuals working with medical fluoroscopic equipment:
 - (1) An individual monitoring device used to determine the dose to an embryo/fetus of a declared pregnant woman, pursuant to **Section C.18(a)(2)**, shall be located under the protective apron at the waist. (Note: It is recognized that, in the specific work environment of medical fluoroscopic equipment, the dose to the embryo/fetus is overestimated by the individual monitoring device because of the overlying tissue of the pregnant individual. A certified expert, such as a medical physicist who is certified by the American Board of Radiology in Diagnostic Radiological Physics or in Radiological Physics should be consulted to determine the dose to the embryo/fetus for the occasions in which this individual monitoring device has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem). Therefore, for purposes of these regulations, the value to be used for determining the dose to the embryo/fetus pursuant to **Section C.13**, for occupational exposure to radiation from medical fluoroscopic equipment may be the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the particular individual and her work environment by a qualified expert.)
 - (2) An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.
 - (3) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to **Section C.6(C)(2)**, it shall be located at the neck outside the protective apron. When a second individual monitoring device is used,

¹² Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

for the same purpose, it shall be located under the protective apron at the waist. (Note: The second individual monitoring device is required for a declared pregnant woman.)

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

Section C.19 Control of Access to High Radiation Areas.

- (a) The registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:
 - (1) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or
 - (2) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or
 - (3) Entry ways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.
- (b) In place of the controls required by **Section C.19(a)** for a high radiation area, the registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.
- (c) The registrant may apply to the Department for approval of alternative methods for controlling access to high radiation area.
- (d) The registrant shall establish the controls required by **Section C.19(a)** and **(c)** in a way that does not prevent individuals from leaving a high radiation area.
- (e) The registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the **U.S. Department of Transportation** provided that:
 - (1) The packages do not remain in the area longer than 3 days; and
 - (2) The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.
- (f) The registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that personnel are in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this Part and to operate within the ALARA provisions of the registrant's radiation protection program.
- (g) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in **Section C.6** for x-rays in the healing arts, and **Section C.9** for particle accelerators.

Section C.20 Control of Access to Very High Radiation Areas.

- (a) In addition to the requirements in **Section C.19**, the registrant shall institute measures to

ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self shielded irradiators.

- (b) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in **Section C.20(a)** if the registrant has met all the specific requirements for access and control specified in other applicable regulations, such as, **Section C.4** for industrial radiography, **Section C.6** for x rays in the healing arts, and **Section C.9** for particle accelerators.

STORAGE AND CONTROL OF REGISTERED SOURCES OF RADIATION

Section C.25 Security of Stored Sources of Radiation.

The registrant shall secure from unauthorized removal or access registered sources of radiation that are stored in controlled or unrestricted areas.

Section C.26 Control of Sources of Radiation Not in Storage.

- (a) The registrant shall control and maintain constant surveillance of licensed radioactive material that is in a controlled or unrestricted area and that is not in storage or in a patient.
- (b) The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.

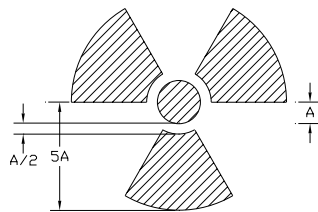
PRECAUTIONARY PROCEDURES

Section C.27 Caution Signs.

- (a) **Standard Radiation Symbol.** Unless otherwise authorized by the Agency, the symbol prescribed by **Section C.27** shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

- (1) Cross-hatched area is to be magenta, or purple, or black, and
- (2) The background is to be yellow.



- (b) **Exception to Color Requirements for Standard Radiation Symbol.** Notwithstanding the requirements of **Section C.27(a)**, registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

- (c) **Additional Information on Signs and Labels.** In addition to the contents of signs and labels prescribed in this Part, the registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

Section C.28 Posting Requirements.

- (a) **Posting of Radiation Areas.** The registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "**CAUTION, RADIATION AREA.**"
- (b) **Posting of High Radiation Areas.** The registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "**CAUTION, HIGH RADIATION AREA**" or "**DANGER, HIGH RADIATION AREA.**"
- (c) **Posting of Very High Radiation Areas.** The registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "**GRAVE DANGER, VERY HIGH RADIATION AREA.**" For each very high radiation area, created in a medical institution by the use of a registered medical particle accelerator, the word "**DANGER**" may be substituted for the words "**GRAVE DANGER**".
- (d) **Posting of Airborne Radioactivity Areas.** The registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "**CAUTION, AIRBORNE RADIOACTIVITY AREA**" or "**DANGER, AIRBORNE RADIOACTIVITY AREA.**"
- (e) **Posting of Areas or Rooms in Which Licensed Radioactive Material is Used or Stored.** The registrant shall post each area or room in which there is used or stored an amount of registered material exceeding 10 times the quantity of such material specified in **Appendix C¹³** with a conspicuous sign or signs bearing the radiation symbol and the words "**CAUTION, RADIOACTIVE MATERIAL(S)**" or "**DANGER, RADIOACTIVE MATERIAL(S).**"

Section C.29 Exceptions to Posting Requirements.

- (a) A registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:
- (1) The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Part; and
 - (2) The area or room is subject to the registrant's control.
- (b) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to **Section C.28** provided that the patient could be released from confinement pursuant to **420-3-26-.07(27)** of these regulations.
- (c) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

¹³ Refers to Appendix C, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

- (d) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

Section C.30 Labeling Containers and Radiation Machines.

- (a) The registrant shall ensure that each container of registered material bears a durable, clearly visible label bearing the radiation symbol and the words "**CAUTION, RADIOACTIVE MATERIAL**" or "**DANGER, RADIOACTIVE MATERIAL.**" The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.
- (b) Each registrant, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.
- (c) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

Section C.31 Exemptions to Labeling Requirements.

A registrant is not required to label:

- (a) Containers holding registered material in quantities less than the quantities listed in **Appendix C¹⁴**; or
- (b) Containers holding registered material in concentrations less than those specified in **Table III of Appendix B¹⁵**; or
- (c) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Part; or
- (d) Containers when they are in transport and packaged and labeled in accordance with the regulations of the **U.S. Department of Transportation**; or
- (e) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or
- (f) Installed manufacturing or process equipment, such as piping and tanks.

RECORDS

Section C.40 General Provisions.

- (a) Each registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall

¹⁴ Refers to Appendix C, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

¹⁵ Refers to Appendix B, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

clearly indicate the units of all quantities on records required by this Part.

- (b) The registrant shall make a clear distinction among the quantities entered on the records required by this Part, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

Section C.41 Records of Radiation Protection Programs.

- (a) Each registrant shall maintain records of the radiation protection program, including:
 - (1) The provisions of the program; and
 - (2) Audits and other reviews of program content and implementation.
- (b) The registrant shall retain the records required by **Section C.41(a)(1)** until the Agency terminates each pertinent license or registration requiring the record. The registrant shall retain the records required by **Section C.41(a)(2)** for 3 years after the record is made.

Section C.42 Records of Surveys.

- (a) Each registrant shall maintain records showing the results of surveys and calibrations required by **Section C.17** and **Section C.32**. The registrant shall retain these records for 3 years after the record is made.
- (b) The registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:
 - (1) Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and
 - (2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and
 - (3) Records showing the results of air sampling, surveys, and bioassays required pursuant to **Section C.24(a)(3)(i) and (ii)**; and
 - (4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.
- (c) Upon termination of the license or registration, the registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

Section C.44 Records of Prior Occupational Dose.

- (a) The registrant shall retain the records of prior occupational dose and exposure history as specified in **Section C.10** on Agency Form Y or equivalent until the Agency terminates each pertinent license or registration requiring this record. The registrant shall retain records used in preparing Agency Form Y or equivalent for 3 years after the record is made.
- (b) Upon termination of the license or registration, the registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

Section C.45 Records of Planned Special Exposures.

- (a) For each use of the provisions of **Section C.11** for planned special exposures, the registrant shall maintain records that describe:
- (1) The exceptional circumstances requiring the use of a planned special exposure; and
 - (2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and
 - (3) What actions were necessary; and
 - (4) Why the actions were necessary; and
 - (5) What precautions were taken to assure that doses were maintained ALARA; and
 - (6) What individual and collective doses were expected to result; and
 - (7) The doses actually received in the planned special exposure.
- (b) The registrant shall retain the records until the Agency terminates each pertinent registration requiring these records.
- (c) Upon termination of the registration, the registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

Section C.46 Records of Individual Monitoring results.

- (a) **Record Keeping Requirement.** Each registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to **Section C.18**, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994 need not be changed. These records shall include, when applicable:
- (1) The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and
 - (2) The estimated intake of radionuclides. See **Section C.7**; and
 - (3) The committed effective dose equivalent assigned to the intake of radionuclides; and
 - (4) The specific information used to calculate the committed effective dose equivalent pursuant to **Section C.9(c)**; and
 - (5) The total effective dose equivalent when required by **Section C.7**; and
 - (6) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.
- (b) **Record Keeping Frequency.** The registrant shall make entries of the records specified in **Section C.46(a)** at intervals not to exceed 1 year.

- (c) **Record Keeping Format.** The registrant shall maintain the records specified in **Section C.46(a)** on Agency Form Z, in accordance with the instructions for Agency Form Z, or in clear and legible records containing all the information required by Agency Form Z.
- (d) The registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.
- (e) The registrant shall retain each required form or record until the Agency terminates each pertinent license or registration requiring the record.
- (f) Upon termination of the license or registration, the registrant shall permanently store records on Agency Form Y or equivalent, or shall make provisions with the Agency for transfer to the Agency.

Section C.47 Records of Dose to Individual Members of the Public.

- (a) Each registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See **Section C.14**.
- (b) The registrant shall retain the records required by **Section C.48(b)** until the Agency terminates each pertinent registration requiring the record.

Section C.49 Records of Testing Entry Control Devices for Very High Radiation Areas.

- (a) Each registrant shall maintain records of tests made pursuant to **Section C.21(b)9**. On entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.
- (b) The registrant shall retain the records required by **Section C.49(a)** for 3 years after the record is made.

Section C.50 Form of Records.

Each record required by this Part shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microfilm, provided that the copy or microfilm is authenticated by authorized personnel and that the microfilm is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The registrant shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

Section C.51 Reports of Stolen Lost, or Missing Registered Sources of Radiation.

- (a) **Telephone Reports.** Each registrant shall report to the Agency by telephone as follows:
 - (1) Immediately after its occurrence becomes known to the registrant stolen, lost, or missing registered radioactive material in an aggregate quantity equal to or greater than 1,000

times the quantity specified in **Appendix C**¹⁶ under such circumstances that it appears to the registrant that an exposure could result to individuals in unrestricted areas; or

- (2) Within 30 days after its occurrence becomes known to the registrant lost, stolen, or missing registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in **Appendix C**¹⁷ that is still missing.
 - (3) Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.
- (b) **Written Reports.** Each registrant required to make a report pursuant to **Section C.51(a)** shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:
- (1) A description of the registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and,
 - (2) A description of the circumstances under which the loss or theft occurred; and
 - (3) A statement of disposition, or probable disposition, of the registered source of radiation involved; and
 - (4) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and
 - (5) Actions that have been taken or will be taken to recover the source of radiation; and
 - (6) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of registered sources of radiation.
- (c) Subsequent to filing the written report, the registrant shall also report additional substantive information on the loss or theft within 30 days after the registrant learns of such information.
- (d) The registrant shall prepare any report filed with the Agency pursuant to **Section C.51** so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

Section C.52 Notification of Incidents.

- (a) **Immediate Notification.** Notwithstanding other requirements for notification, each registrant shall immediately report each event involving a source of radiation possessed by the registrant that may have caused or threatens to cause any of the following conditions:
- (1) An individual to receive:
 - (i) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or
 - (ii) An eye dose equivalent of 0.75 Sv (75 rem) or more; or

¹⁶ Refers to Appendix C, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

¹⁷ Refers to Appendix C, Chapter 420-3-26-.03 of the Rules of State Board of Health Bureau of Health Care Standards.

- (iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or
 - (2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.
- (b) **Twenty-four Hour Notification.** Each registrant shall, within 24 hours of discovery of the event, report to the Agency each event involving loss of control of a registered source of radiation possessed by the registrant that may have caused, or threatens to cause, any of the following conditions:
- (1) An individual to receive, in a period of 24 hours:
 - (i) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or
 - (ii) An eye dose equivalent exceeding 0.15 Sv (15 rem);
 - (iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or
 - (2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.
- (c) The registrant shall prepare each report filed with the Agency pursuant to **Section C.52** so that names of individuals who have received exposure to sources of radiations are stated in a separate and detachable portion of the report.
- (d) Registrants shall make the reports required by **Section C.52(a) and (b)** to the Agency by telephone, telegram, mailgram, or facsimile to the Agency.
- (e) The provisions of **Section C.52** do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to **Section C.54**.

Section C.53 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

- (a) **Reportable Events.** In addition to the notification required by **Section C.52**, each registrant shall submit a written report within 30 days after learning of any of the following occurrences:
- (1) Incidents for which notification is required by **Section C.52**; or
 - (2) Doses in excess of any of the following:
 - (i) The occupational dose limits for adults in **Section C.6**; or
 - (ii) The occupational dose limits for a minor in **Section C.12**; or

- (iii) The limits for an embryo/fetus of a declared pregnant woman in **Section C.13**; or
 - (iv) The limits for an individual member of the public in **Section C.14**; or
 - (v) Any applicable limits in the registrations; or
- (3) Levels of radiation or concentrations of radioactive material in:
- (i) A restricted area in excess of applicable limits in the license or registration; or
 - (ii) An unrestricted area in excess of 10 times the applicable limits set forth in this Part or in the registration, whether or not involving exposure of any individual in excess of the limits in **Section C.14**; or
- (4) For registrants subject to the provisions of **U.S. Environmental Protection Agency's** generally applicable environmental radiation standards in **40 CFR 190**, levels of radiation or releases of radioactive material in excess of those standards, or of registration conditions related to those standards.
- (b) **Contents of Reports.**
- (1) Each report required by **Section C.53(a)** shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:
 - (i) Estimates of each individual's dose; and
 - (ii) The levels of radiation and concentrations of radioactive material involved; and
 - (iii) The cause of the elevated exposures, dose rates, or concentrations; and
 - (iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated registration conditions.
 - (2) Each report filed pursuant to **Section C.53(a)** shall include for each individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in **Section C.13**, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.
- (c) All registrants who make reports pursuant to **Section C.53(a)** shall submit the report in writing to the Agency.

Section C.54 Reports of Planned Special Exposures.

The registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with **Section C.11**, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by **Section C.45**

Section C.55 (Reserved).

Section C.56 Reports of Individual Monitoring.

- (a) This section applies to each person registered by the Department to:

- (1) Possess or use sources of radiation for purposes of industrial radiography pursuant to **420-3-26-.02(10)(g)** and **420-3-26-.04** of these regulations; or
- (b) Each registrant in a category listed in **Section C.56** shall submit an annual report of the results of individual monitoring carried out by the registrant for each individual for whom monitoring was required by **Section C.18** during that year. The registrant may include additional data for individuals for whom monitoring was provided but not required. The registrant shall use Agency Form Z or equivalent or electronic media containing all the information required by Agency Form Z.
- (c) The registrant shall file the report required by **Section C.56(b)**, covering the preceding year, on or before April 30 of each year. The registrant shall submit the report to the Agency.

Section C.57 Notifications and Reports to Individuals.

- (a) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in **420-3-26-.04** of these regulations.
- (b) When a registrant is required pursuant to **Section C.53** to report to the Agency any exposure of an individual to radiation or radioactive material, the 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 **420-3-26-.04(a)** of these regulations.

Author: James D. Archer, Jr., Environmental Health Program Supervisor.

Authority: §§; 22-2-1, 22-2-2, 22-2-5, and 22-2-6; and 22-3-4; also 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, Code of Alabama, 1975.

History: Promulgated Jan. 1, 1961; revised Sept. 1, 1969; Nov. 1, 1971; revised Oct. 1, 1977; revised June 10, 1981; revised Aug. 12, 1986; revised NOV. 9, 1994.

PART D

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Section D.1: Purpose.

The regulations in this Part establish radiation safety requirements for persons utilizing ionizing radiation for industrial radiography. The requirements of this Part are in addition to, and not in substitution for, the requirements of these regulations.

Section D.2: Scope.

The requirements of this Part apply to all registrants who use ionizing radiation producing machines for industrial radiography; provided, however, that nothing in this Part shall apply to use of sources of ionizing radiation in the healing arts.

Section D.3: Definitions.

Definitions as used in this Part are found in the Glossary.

Section D.4: Locking Of Sources Of Radiation.

- (a) Each source of ionizing radiation shall be provided with a lock designed to prevent unauthorized or accidental production of ionizing radiation, and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer's assistant, or as may otherwise be authorized pursuant to **Section D.10**.
- (b) Radiographic exposure devices, prior to being moved from one location to another and prior to being secured at a given location, shall be locked.

Section D.5: Radiation Survey Instruments.

- (a) The registrant shall maintain sufficient calibrated and operable x-ray survey instruments to make physical radiation surveys required by this Part and **Part C** of these regulations. Instruments required by this Section shall have a range such that two (2) milliroentgens per hour through one (1) roentgen per hour can be measured.
- (b) Each radiation survey instrument shall be calibrated:
 - (1) At energies appropriate for the use and at intervals not to exceed three (3) months and after each instrument servicing;
 - (2) Such that accuracy within ± 20 percent can be demonstrated; and
 - (3) At two or more widely separated points, other than zero, on each scale.
- (c) Records shall be maintained of these calibrations for two (2) years after the calibration date for inspection by the Department.

Section D.6: Quarterly Inventory.

Each registrant shall conduct a quarterly physical inventory to account for all sources of radiation received or possessed by him. The records of inventories shall be maintained for inspection by the Department and shall include the quantities and type of radiation producing equipment, the location of all sources of radiation, and the date of the inventory. Records of these inventories

shall be maintained for two (2) years.

Section D.7: Utilization Log.

Each registrant shall maintain current logs, which shall be kept available for two (2) years from the date of the recorded event, for inspection by the Department, at the address specified in the registration, showing for each source of ionizing radiation:

- (a) The make, model and control serial number of each industrial x-ray machine;
- (b) The identity of the radiographer to whom assigned;
- (c) The plant or site where used; and
- (d) The date of use.

PERSONAL RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHERS AND RADIOGRAPHER'S ASSISTANTS

Section D.8: Limitations.

- (a) No registrant shall permit any person to act as a radiographer, as defined in the Glossary, until such person:
 - (1) Has been instructed in the subjects outlined in **APPENDIX A** to this Part, and shall have demonstrated understanding thereof;
 - (2) Has received copies of and instruction in the regulations contained in this Part and the applicable Sections of **Parts C and F** and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;
 - (3) Has demonstrated competence to use the source of ionizing radiation and survey instruments which will be employed in his assignment; and
 - (4) Has demonstrated understanding of the instructions in this paragraph by successfully completing a written or oral test and a field examination of the subjects covered.
- (b) No registrant shall permit any person to act as a radiographer's assistant, as defined in the Glossary, until such person:
 - (1) Has received copies of and instruction in the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;
 - (2) Has demonstrated competence to use, under the supervision of the radiographer, the source of ionizing radiation and survey instruments which will be employed in his assignment; and
 - (3) Has demonstrated understanding of the instructions in this paragraph by successfully completing a written or oral test and a field examination of the subjects covered.
- (c) Each registrant shall maintain records of training and testing which demonstrate that the requirements of **Section D.8** are met for inspection by the Department for three (3) years following the termination of employment of the individual.
- (d) The requirements of this Section shall be deemed met if the Alabama State Department of Health states that the person in question has qualified as a radiographer or radiographer's

assistant in compliance with its regulations.

Section D.9: Operating And Emergency Procedures.

The registrant's operating and emergency procedures shall include instructions in at least the following:

- (a) The handling and use of sources of ionizing radiation to be employed such that no person is likely to be exposed to ionizing radiation doses in excess of the limits established in **Part C**, "Standards For Protection Against Radiation;"
- (b) Methods and occasions for conducting radiation surveys;
- (c) Methods for controlling access to radiographic areas;
- (d) Personnel monitoring and the use of personnel monitoring equipment;
- (e) Procedures for notifying proper persons in the event of an accident; and
- (f) Maintenance of records.

Section D.10: Personnel Monitoring Control.

- (a) The registrant shall not permit any person to act as a radiographer or as a radiographer's assistant unless at all times during radiographic operations each such person shall wear a direct-reading pocket dosimeter and either a film badge or thermoluminescence dosimeter (TLD). 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 and thermoluminescence dosimeter shall be assigned to and worn by only one person.
- (b) Pocket dosimeters and pocket chambers shall be read and doses recorded daily.
- (c) If an individual's pocket dosimeter is discharged beyond its range, his film badge or TLD shall immediately be sent for processing.
- (d) Pocket dosimeters shall be checked at periods not to exceed six (6) months for correct response to radiation. Acceptable dosimeters shall read within \pm 30 percent of the true radiation exposure.
- (e) Reports from any film badge or TLD processor and records of daily pocket dosimeter readings shall be kept for inspection by the Department until it authorizes their disposal.

Section D.11: Supervision Of Radiographer's Assistant.

Whenever a radiographer's assistant uses radiographic exposure devices or conducts radiation surveys required by **Section D.14** to determine that an x-ray producing machine is off, he shall be under the personal supervision of a radiographer. The personal supervision shall include:

- (a) The radiographer's physical presence at the site where the x-ray machine is being used;
- (b) The ability of the radiographer to give immediate assistance if required; and
- (c) The radiographer's watching the assistant's performance of the operations referred to in this Section.

PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

Section D.12: Security.

During each radiographic operation the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized or accidental entry into a high radiation area, except where the high radiation area is:

- (a) Equipped with a control device or an alarm system, as described in **Part C**; or
- (b) Locked to protect against unauthorized or accidental entry, as described in **Part C**.

Locked radiographic devices shall be physically secured to prevent tampering or removal by unauthorized personnel.

Section D.13: Posting.

Areas in which radiography is being performed shall be conspicuously posted, as described in **Part C**.

Section D.14: Radiation Surveys And Survey Records.

No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in **Section D.5**, is available and used at each site where radiographic exposures are being made.

Section D.15: Special Requirements And Exemptions.

- (a) **Cabinet Radiography.** Cabinet radiography using x-ray producing machines, as defined in the Glossary, shall be exempt from other requirements of this Part; however, no registrant shall permit any person to operate a cabinet radiography unit until such individual has received a copy of and instruction in, and has demonstrated an understanding of operating procedures for such unit and has demonstrated competence in its use.
- (b) **Shielded Room Radiography.** Shielded room radiography using radiation producing machines, as defined in the Glossary, shall be exempt from other requirements of this Part; however:
 - (1) No registrant shall permit any individual to operate an x-ray producing machine for shielded room radiography until such individual has received a copy of and instruction in, and has demonstrated an understanding of operation procedures for the unit;
 - (2) Each registrant shall supply appropriate personnel monitoring equipment to and shall require the use of such equipment by every individual who makes "setups," or who operates or performs maintenance on an x-ray producing machine or shielded room radiography;
 - (3) A physical radiation survey shall be conducted to demonstrate that the x-ray producing machine is "off" prior to each entry into the shielded room. Such surveys shall be made with a radiation measurement instrument which meets the requirements of **Section D.5**.
- (c) **Other Radiography Using X-ray Producing Machines.**
 - (1) A physical radiation survey shall be conducted to demonstrate that the x-ray producing machine is "off" prior to each entry into the radiographic exposure area. Such surveys shall be made with a radiation measurement instrument which meets the requirements of **Section D.5**.

- (2) Survey results and records of boundary locations shall be maintained and kept available for inspection.
- (3) Mobile or portable x-ray producing machines shall be physically secured to prevent removal by unauthorized personnel.

Author: James D. Archer, Jr., Environmental Health Program Supervisor.

Authority: §§; 22-2-1, 22-2-2, 22-2-5, and 22-2-6; and 22-3-4; also 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, Code of Alabama, 1975.

History: Promulgated Jan. 1, 1961; revised Sept. 1, 1969; Nov. 1, 1971; revised Oct. 1, 1977; revised June 10, 1981; revised Aug. 12, 1986; revised NOV. 9, 1994.

APPENDIX A

INSTRUCTION OF RADIOGRAPHERS

I. Fundamentals of Radiation Safety.

- A. Characteristics of Gamma and 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 Distance.
 - 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. Pocket Chambers.

III. Radiographic Equipment to be Used. Operation and Control of X-ray Equipment.

IV. The Requirements of Pertinent Federal, State, and County Regulations.

V. The Registrant's Written Operating and Emergency Procedures.

PART E

RADIATION SAFETY REQUIREMENTS FOR USERS OF X-RAYS IN HEALING ARTS OR SERVICERS OF X-RAY EQUIPMENT

Section E.1: Scope.

Part C establishes standards for the use of x-rays in the healing arts including, but not limited to, medicine, dentistry, osteopathy, chiropractic, podiatry, veterinary medicine, and x-ray service. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of these regulations. For certified x-ray systems, no provisions of these regulations shall differ from the **Federal Performance Standards codified in 21 CFR Subchapter J**. Periodic inspection will be performed of all registrants.

Section E.2: Definitions.

Definitions as used in this Part are found in the Glossary.

Section E.3: General Requirements.

(a) The Department may waive compliance with the specific requirements of this Part by an existing machine or installation if:

- (1) Such compliance would require replacement or substantial modification of the machine or installation; and
- (2) The registrant demonstrates to the Department's satisfaction and achievement through other means radiation protection equivalent to that required by these regulations.

(b) Administrative Controls.

(1) **Registrant.** The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of **Section E.3(b)(1)** are met in the operation of the x-ray system(s).

- (i) An x-ray system that does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes if so directed by the Department.
- (ii) Individuals who will be operating the x-ray system(s) shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.
- (iii) 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) The patient's anatomical size versus technique factor to be utilized;
- (b) The type and size of film or film-screen combination to be used;
- (c) The type and focal distance of the grid to be used, if any;
- (d) The Source-to-Image-Distance (SID) receptor distance to be used; and

- (e) The type and location of placement of gonad shielding to be used.
- (iv) Written safety procedures shall be provided to each individual operating x-ray equipment, including any restrictions required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.
- (v) Except for patients, who cannot be removed from 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 in the room at the time of the exposure shall be positioned such that no part of the body, including the extremities, not protected by 0.5 mm of lead equivalent will be struck by the useful beam unless protected by 0.5 mm of 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 mm of lead equivalent:
 - (c) Patients, who cannot be removed from the room, shall be protected from direct scatter radiation by whole body protective barriers of 0.25 mm of lead equivalent, or shall be so positioned that the nearest portion of the body is at least two (2) meters from both the tube head and the nearest edge of the image receptor.
- (vi) Gonad shielding of not less than 0.25 mm of lead equivalent shall be used for patients who have not passed the reproductive age at the time of any radiographic exposure in which the gonads are in the direct useful beam, except for the case in which this would interfere with the diagnostic procedure.
- (vii) Persons shall not be exposed to the useful beam except for healing arts purposes, and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
 - (a) Exposure of an individual for the purposes of training, demonstration, or other non-healing-arts purposes unless there are also healing arts requirements and a proper prescription has been provided; and
 - (b) Exposure of an individual for the purposes of healing arts screening unless authorized by **Section E.3(b)(1)(xi)**. When requesting approval, that person shall submit the information outlined in **APPENDIX A** to this Part. If any of the information submitted to the Department becomes invalid or outdated, the Department shall immediately be notified.
- (viii) When a patient or film must be provided with auxiliary support during radiation exposures:
 - (a) Mechanical holding devices shall be used when the technique permits. The written safety procedures required by **Section E.3(b)(1)(iv)** shall list the individual projections where holding devices cannot be utilized;
 - (b) Written safety procedures as required by **Section E.3(b)(1)(iv)** shall indicate the requirements for selecting an individual to hold patients and the procedure the holder shall follow;

- (c) The human holder shall be protected as required by **Section E.3(b)(1)(v)**;
 - (d) No individual shall be used routinely to hold film or patients; and
 - (e) In any case where the patient must hold the film, except during intraoral examinations, 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 mm of lead equivalent material.
- (ix) **Personnel Monitoring.**
- (a) Each registrant shall provide personnel monitoring devices which shall be used by each individual who:
 - (1) Receives or is likely to receive a whole body dose in excess of 25 milliroentgens per week;
 - (2) Enters a high radiation area;
 - (3) Operates mobile x-ray equipment;
 - (4) Operates photofluoroscopic equipment; and/or
 - (5) Services an operable x-ray machine.
 - (x) All individuals who are associated with the operation of an x-ray system are subject to the requirements of **Part C** of these regulations. In addition:
 - (a) When protective clothing or devices are worn on portions of the body and a monitoring device is required, at least one such device shall be utilized as follows:
 - (1) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron; and
 - (2) The dose to the whole body based on the maximum dose attributed to any critical organ (gonads, blood forming organs, head and trunk, or lens of the eye) shall be recorded in the reports required by **Part C**. If more than one device is used and a record is made of the data, each dose shall be identified with the area of the body where the device is worn.
 - (b) Exposure of personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.
 - (xi) **Healing Arts Screening.** Any person proposing to conduct a healing arts screening program shall not initiate such program without prior written approval of the Department. When requesting such approval, that person shall submit the information outlined in **APPENDIX A** to this Part. If any information submitted to the Department becomes invalid or outdated, the Department shall be notified immediately.
- (2) Information and Maintenance of Records and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the Department:
- (i) Maximum rating of technique factors:

- (ii) Model and serial numbers of all certifiable components;
 - (iii) Aluminum equivalent filtration of the useful beam, including any routine variation;
 - (vi) Tube rating charts and cooling curves;
 - (v) Records of surveys, calibration, maintenance, and modifications performed on the x-ray system(s) after the effective date of **Section E.3** with the names of persons who performed such surveys;
 - (vi) 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 occupancy by an individual in such area. In addition, the drawing shall include:
 - (a) The results of a survey of radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
 - (b) The type and thickness of materials, or lead equivalency, of each protective barrier; and
 - (vii) A copy of all correspondence with this Department regarding that x-ray system.
- (3) **X-ray Log.** Each facility shall maintain an x-ray log containing the patient's name, the type of examination, number of films taken, the name of the human holder, the initials of the technologist, the date the examination was performed, and the number of exposures for which the patient was held.
- (c) **Use.** The registrant shall be responsible for assuring that:
- (1) All applicable requirements of **Part C** of these regulations are met; and
 - (2) All x-ray equipment under his control is operated by individuals adequately trained in safe operating procedures and competent in the proper use of the equipment.
 - (3) After October 1, 1974, no registrant who services x-ray producing equipment shall permit any person to service such equipment, when operable, until such person has been appropriately instructed in the subjects outlined in **APPENDIX A to Part B** of these regulations and shall have demonstrated an understanding thereof.
 - (4) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objectives of the examination.
 - (5) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.
- (d) **Shielding.**
- (1) Entrances from a unrestricted areas into rooms utilizing x-rays for diagnostic or therapeutic purposes shall have :
 - (i) Warning lights electrically interlocked to the rotors of diagnostic-type tube housing to warn of exposures about to be taken; and
 - (ii) Warning lights and door electrically interlocked to the beam-on circuitry for each room used for x-ray therapy to prevent accidental exposure.

- (2) Each installation shall be provided with such primary barriers and/or secondary barriers as are necessary to assure compliance with applicable sections of **Part C**. This requirement shall be deemed to be met if the thickness of such barriers is equivalent to those as computed in accordance with the **National Council on Radiation Protection and Measurements Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies up to 10 MeV,"** and the **National Council on Radiation Protection and Measurements Report No. 35, "Dental X-ray Protection."**
- (e) **Darkroom Requirements.** To reduce unnecessary re-exposure of patients resulting from film processing problems:
 - (1) The darkroom shall be lightproof;
 - (2) The area in which undeveloped films are handled for processing shall be devoid of light, during handling and processing, with the exception of light in the wave lengths having no specific effects on the radiographic film.
 - (3) A thermometer and timer operable and appropriate for the type film processing shall be in use in the darkroom. The use of properly maintained automatic film processing equipment shall meet the requirements of this paragraph for all film so processed.
- (f) Unexposed x-ray film shall be stored in a location such that the film will not be exposed to x-radiation in amounts sufficient to impair the quality or usefulness of such film.
- (g) All x-ray equipment shall be electrically grounded.

Section E.4: General Requirements For All Diagnostic X-ray Equipment.

In addition to other requirements of this Part, all diagnostic x-ray equipment shall meet the following requirements:

- (a) **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.**"
- (b) **Battery Charge Indicator.** On battery powered x-ray generators, visual means shall be provided on the control panel to indicate whether or not the battery is in a state of charge adequate for proper operation.
- (c) **Leakage Radiation from the Diagnostic Source Assembly.** The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed 100 milliroentgens in one (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 twenty (20) centimeters.
- (d) **Radiation from Components Other Than the Diagnostic Source Assembly.** The radiation emitted by a component other than the diagnostic source assembly shall not exceed two (2) milliroentgens in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any condition 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 twenty (20) centimeters.

(e) **Beam Quality.**(1) **Half-value Layer.**

- (i) The half-value layer for a given x-ray tube potential shall not be less than the value 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.
- (ii) The requirements of **Section E.4(e)(1)(i)** will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.
- (iii) In addition to the requirements of **Section E.4(e)(1)(i)**, all intraoral radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer of not less than 1.5 millimeters aluminum equivalent filtration permanently installed in the useful beam.
- (iv) Beryllium window tubes shall have a minimum of 0.5 millimeter of aluminum equivalent filtration permanently installed in the useful beam.

Table I

Designed Operating Range	Measured Potential (kVp)	Half-Value Layer in mm AL
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	

Table II
Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	Total Filtration (inherent plus added) in mm Al Equivalent
Below 50	0.5
50 to 70	1.5
Above 70	2.5

- (v) For capacitor energy storage equipment, compliance with the **Section E.4(e)** shall be determined with the maximum quantity of charge per exposure.
- (vi) The required minimal aluminum equivalent filtration shall include the filtration contributed by all material which are always present between the source and the patient.
- (2) **Filtration Controls.** 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 **Section E.4(e)(1)** is in the useful beam for the given kVp which has been selected.
- (f) **Multiple Tubes.** When 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 the initiation of exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.
- (g) **Mechanical Support of the Tube Head.** The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during the exposure unless the tube housing movement is a designed function of the x-ray system.
- (h) **Technique Indicators.**
 - (1) The technique factor to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.
 - (2) The requirements of **Section E.4(h)(1)** 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.

Section E.5: Fluoroscopic X-ray Systems.

All Fluoroscopic x-ray systems shall meet the following requirements.

- (a) **Limitation of the Useful Beam.**
 - (1) **Primary Barrier.** The tube housing shall be of diagnostic type.
 - (i) The fluoroscopic image assembly shall be provided with a primary protective barrier which intercepts the entire cross-section of the useful beam at any source-to-image distance (SID).
 - (ii) The fluoroscopic tube shall not produce x-rays unless the primary barrier is in position to intercept the entire useful beam.

- (2) **x-ray Field.** Limitation to imaging surface.
- (i) **Nonimage-Intensified Fluoroscopy and Spot Filming.** The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic and spot-filming procedures. In addition:
- (a) Means shall be provided for stepless adjustment of the field size;
 - (b) The minimum field size at the greatest SID shall be equal to or less than 5 X 5 centimeters;
 - (c) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the beam axis is perpendicular to the plane of the image receptor; and
 - (d) Compliance with **Section E.5(a)(2)(i)** shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- (ii) **Image-Intensified Fluoroscopy and Spot Filming.** 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 that of the visible area of the image receptor by more than three (3) percent of the SID. The sum of the excess length and excess width shall be no greater than four (4) percent of the SID. In addition:
- (a) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area greater than 300 square centimeters shall be provided with a means of stepless adjustment of the x-ray field;
 - (b) All equipment with a fixed SID and a visible area of 300 centimeters or less shall be provided with either stepless adjustment of the x-ray field or a means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall provide, at the greatest SID, continuous field size from the maximum obtainable to a field size of 5 X 5 centimeters or less;
 - (c) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the beam axis is perpendicular to the plane of the image receptor; and
 - (d) Compliance with **Section E.5(a)(2)(ii)** shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields 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.
- (iii) Spot-film devices which are certified components shall meet the following additional requirements:
- (a) Means shall be provided between the source and the patient for the adjustment of the x-ray field in the plane of the film to be the size of that portion of film which

has been selected on the spot-film selector. Such adjustment shall be automatic except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 30, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the film size shall be only at the operator's option;

- (b) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to or less than 5 X 5 centimeters;
 - (c) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two (2) percent of the SID; and
 - (d) On spot-film devices manufactured after February 25, 1978, if the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the beam axis is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- (b) **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 a series in process.
- (c) **Exposure Rate Limits.**
- (1) **Entrance Exposure Rate Allowable Limits.**
 - (i) The exposure rate when measured at the point where the center of the useful beam enters the patient shall not exceed ten (10) roentgens per minute except during the recording of fluoroscopic images or when providing optional high level controls.
 - (ii) When provided with optional high level controls, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five (5) roentgens per minute where the center of the useful beam enters the patient unless the high level control is activated.
 - (a) Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. The high level control shall be only operable when continuous manual activation is provided by the operator.
 - (b) A continuous audible signal to the fluoroscopist shall indicate that the high level control is being employed.
 - (iii) In addition to the other requirements of **Section E.5**, certified equipment which does not incorporate automatic exposure control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five (5) roentgens per minute at the point where the center of the beam enters the patient except during the recording of fluoroscopic images or when providing optional high level controls.
 - (iv) Compliance with **Section E.5(c)** shall be determined as follows:

- (a) Moveable grids and compression devices shall be removed from the useful beam during the measurement.
 - (b) If the source is below the table, the exposure rate shall be measured one (1) centimeter above the tabletop or cradle.
 - (c) If the source is above the table, the exposure rate shall be measured thirty (30) centimeters above the tabletop with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement.
 - (d) In a C-Arm type of fluoroscope, the exposure rate shall be measured thirty (30) centimeters from the input surface of the imaging assembly.
- (v) Periodic measurements of entrance exposure rate shall be performed as follows:
- (a) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.
 - (b) 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 **Section E.3(b)(2)(v)**. The measurement results shall be stated in roentgens per minute and shall include the technique factors used in determining the results. The name of the person performing the measurement and the date the measurements were performed shall be included in the results.
 - (c) Personnel monitoring devices may be used to perform the measurements required by **Section E.5(c)(1)(v)(a)**, provided the measurements are made as described in **Section E.5(c)(1)(v)(d)**.
 - (d) Conditions of periodic measurements of entrance exposure rate are as follows:
 - (1) The measurements shall be made under the conditions that satisfy the requirements of **Section E.5(c)(1)(iv)**;
 - (2) The kVp shall be kVp typical of the x-ray system;
 - (3) The x-ray system(s) that incorporate automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the x-ray system; and
 - (4) X-ray system(s) that do not incorporate automatic exposure control shall utilize a milliamperage typical of the clinical use of the x-ray system.
- (d) **Barrier Transmitted Radiation Rate Limits.**
- (1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam combined with the radiation from the image intensifier, if provided, shall not exceed two (2) milliroentgens per minute of entrance exposure rate per hour at ten (10) centimeters from any accessible surface of the fluoroscopic image assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
- (2) **Measuring Compliance of Barrier Transmission.**
- (i) The exposure rate due to transmission through the primary protective barrier combined with the radiation from the image intensifier shall be determined by

measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

- (ii) If the source is below the tabletop, the measurement shall be made with the fluoroscopic imaging assembly positioned thirty (30) centimeters above the tabletop.
 - (iii) 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 thirty (30) centimeters.
 - (iv) Moveable grids and compression devices shall be removed from the useful beam during the measurement.
 - (v) The attenuation block shall be positioned in the useful beam ten (10) centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic image assembly.
- (e) **Indication of Potential and Current.** During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.
- (f) **Source-to-Skin Distance (SSD).** The SSD shall not be less than:
- (1) 15 inches (38 centimeters) on stationary fluoroscopes installed after the effective date of these regulations;
 - (2) 14 inches (35.5 centimeters) on stationary fluoroscopes which were in operation prior to the effective date of these regulations;
 - (3) 12 inches (30 centimeters) on all mobile fluoroscopes; and
 - (4) 8 inches (20 centimeters) for image-intensified fluoroscopes used for specific surgical applications. When so operated, the registrant must set forth warnings and precautions with respect to the optional means of spacing. The written safety procedures must provide precautionary measures to be adhered to during the use of this device.
- (g) **Fluoroscopic Timer.** A manual-reset, cumulative timing device shall be used which shall either indicate elapsed time by an audible signal or turn off the apparatus when the total exposure exceeds a predetermined limit on one or a series of exposures. The device shall have a maximum time range of five (5) minutes.
- (1) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.
 - (2) 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.
- (h) **Mobile Fluoroscopes.** In addition to the requirements of Section E.5, mobile fluoroscopes shall provide intensified imaging.
- (i) **Control of Scattered Radiation.**
- (1) 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 scatter radiation which originates under the table. The attenuation required shall not be less than 0.25 millimeters of lead equivalent.

- (2) Equipment configuration when combined with the procedures shall be such that no unprotected part of any staff or ancillary individual's body, except the extremities, shall be exposed to unattenuated scattered radiation emanating from above the table top unless:
 - (i) That individual is at least 120 centimeters from the center of the useful beam; or
 - (ii) The radiation has passed through not less than 0.25 millimeters of lead equivalent material including, but not limited to, drapes, buckey-slot cover panel, or self supporting curtains in addition to any lead equivalency provided by the protective apron referred to in **Section E.3(b)(1)(v)**.
- (3) The Department may grant exemptions from **Section E.5(i)(2)** in some special procedures where a sterile field will not permit the use of the normal protective barriers; however, where the use of pre-fitted sterilized covers for the barriers is practical, the Department shall not permit such exemptions.
- (j) **Radiation Therapy Simulation Systems.** Radiation therapy simulation systems shall be exempt from all the requirements of **Sections E.5(a), (c), (d) and (g)** provided that:
 - (1) Such systems are designed and used in such a manner that no individual is in the x-ray room during periods of time when the system is producing x-rays; and
 - (2) Systems which do not meet the requirements of **Section E.5(g)** are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.
- (k) **Total Filtration.** The total filtration permanently in the useful beam shall not be less than 2.5 millimeters aluminum equivalent. This requirement may be assumed to have been met if the half-value layer is not less than 2.5 millimeters of aluminum at normal operating voltages.

Section E.6: Radiographic Installations Other Than Fluoroscopic, Intraoral Dental and Veterinary Medicine.

(a) Beam Limitation.

- (1) The tube housing shall be of diagnostic type.

(2) General Purpose Stationary and Mobile X-ray Systems.

- (i) Fixed cones shall be limited to radiographic equipment designed for only one image receptor size at a fixed SID. Means shall be provided to limit the x-ray field at the plane of the image receptor to dimensions no greater than those of the image receptor plus two (2) inches, and to align the center of the x-ray field with the center of the image receptor to within one (1) inch when measured at 72 inches. There shall be provided a means for stepless adjustment of the x-ray field.
- (ii) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the visually defined field with respect to the edges of the x-ray field along either the length or width of the visually defined field shall not exceed two (2) percent of the SID when the surface on which it appears is perpendicular to the axis of the x-ray beam.

- (iii) The Department may grant exemptions on noncertified x-ray systems from **Section E.6(a)(2)(i)** and **(ii)** provided the registrant makes a written application for such exemption and in that application the registrant:
 - (a) Demonstrates it is impractical to comply with **Section E.6(a)(2)(i)** and **(ii)**; and
 - (b) Demonstrates that the purpose of **Section E.6(a)(2)(i)** and **(ii)** meets the following requirement:
 - (1) The total misalignment of the visually defined field with respect to the edges of the x-ray field along either the length or width of the visually defined field shall not exceed two (2) inches at a 72-inch SID when the surface on which it appears is perpendicular to the axis of the x-ray beam.
- (3) **Additional requirements for Stationary General Purpose X-ray Systems.** In addition to the requirements of **Section E.6(a)(1)**, all stationary general purpose x-ray equipment shall meet the following requirements:
 - (i) A method shall be provided to indicate when the beam axis 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 two (2) percent of the SID, and to indicate the SID to within two (2) percent;
 - (ii) The beam limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and
 - (iii) The indication of field size dimensions and SID's 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 two (2) percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.
- (4) **x-ray Designed for One Image Receptor Size.** Radiographic 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 two (2) percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
- (5) **Systems Designed for or Provided with Special Attachments for Mammography.** Radiographic systems designed only for the purpose of mammography and general purpose radiographic systems, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond the edge of the image receptor by more than two (2) percent of the SID. This requirement can be met with a system which performs as described in **Section E.6(a)(6)(iii)**. When the beam limiting device and the image receptor device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in **Section E.6(a)(6)(iii)(a)** and **(b)** shall be the maximum SID for which the beam limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(6) Special Purpose X-ray Systems.

- (i) Means shall be provided 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 two (2) percent of the SID when the x-ray beam axis is indicated to be perpendicular to the plane of the image receptor.
- (ii) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two (2) percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.
- (iii) **Section E.6(b)(6)(i)** and **(ii)** may be met with a system that meets the requirements of **Section E.6(a)(2)** or when alignment means are also provided may be met with either:
 - (a) An assortment of removable, fixed aperture, beam limiting devices sufficient to meet the requirements 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
 - (b) A beam limiting device having multiple fixed apertures sufficient to meet the requirements 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.

(b) Radiation Exposure Control Devices.

- (1) **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.
- (2) **x-ray Control.**
 - (i) 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:
 - (a) Exposure of 0.5 seconds or less; or
 - (b) During a serial radiography when means shall be provided to permit completion of any single exposure of the series in process.
 - (ii) Each x-ray control shall be located in such a way as to meet the following requirements:
 - (a) Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and
 - (b) Mobile and portable x-ray systems which are:
 - (1) Used for greater than one (1) week in one location (i.e., a room or suite) shall meet the requirements of **Section E.6(b)(2)(ii)(a)**;
 - (2) Used for greater than one (1) hour and less than one (1) week at the same

location (i.e., a room or suite) shall meet the requirements of **Section E.6(b)(2)(b)(1)** or be provided with a 6.5 feet (1.98 m) high protective barrier which is placed at least six (6) feet (1.83 m) from the tube housing assembly and at least six (6) feet (1.83 m) from the patient; or

(3) Used to make an exposure(s) of a patient at the use location shall meet the requirements of **Section E.6(b)(2)(ii)(b)(1)** or **(2)**, or be provided with a method of x-ray control which will permit the operator to be at least twelve (12) feet (3.66 m) from the tube housing assembly during exposure.

(c) 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.

(3) **Automatic Exposure Controls.** When an automatic exposure control is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two (2) pulses;

(iii) The minimum exposure time for all equipment other than that specified in Section E.6(b)(3)(ii) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver five (5) mAs, whichever is greater;

(iv) Either the product of the peak x-ray tube potential, current, and exposure time shall be limited to not more than 60kWs per exposure, or the product of the x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except that, when the x-ray tube potential is less than 50 kVp, the product of the x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(v) A visible signal shall indicate when the exposure has been terminated at the limits required by **Section E.6(b)(3)(iv)**, and manual resetting shall be required before further automatically timed exposures can be made.

(4) **Reproducibility.** With a timer setting of 0.5 second or less, the average exposure period (T_{avg}) shall be greater than or equal to five (5) times the maximum exposure period (T_{max}) minus the minimum exposure:

$$\left| X_{avg1} - X_{avg2} \right| \leq \left| X_{avg1} + X_{avg2} \right|$$

$$T_{avg} \geq 5(T_{max} - T_{min}).$$

(c) **Source-to-Skin Distance (SSD).** All mobile and portable radiographic systems shall be provided with means to limit the SSD to equal to or greater than thirty (30) centimeters.

(d) **Exposure Reproducibility.** The coefficient of variation of exposure 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 (E_{avg}) is greater than or equal to five (5) times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

Eavg - 5(Emax - Emin).

- (e) **Radiation from Capacitor Energy Storage 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 two (2) milliroentgens per hour at five (5) centimeters from any accessible surface of the diagnostic source assembly with the beam limiting device fully open.
- (f) **Additional Requirements Applicable to Certified Systems Only.** Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).
- (1) **Reproducibility.** When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, the estimated coefficient of variation of radiation exposure shall be no greater than 0.05 for any specific combination of selected technique factors.
 - (2) **Linearity.** When the equipment allows a choice of x-ray tube current settings and is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential in the range of 40 to 100 percent of the maximum rating, the average ratio of exposure to the indicated milliamperere seconds product obtained by any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum;

$$|X_{avg1} - X_{avg2}| \leq 0.10 (X_{avg1} + X_{avg2})$$

where X_{avg1} and X_{avg2} are the average mR/mAs (microcoulomb/kilogram per mAs) values obtained at each of two (2) consecutive tube current settings.

- (3) **Accuracy.** Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
- (4) **Beam Limitation for Stationary and Mobile General Purpose X-ray Systems.**
 - (i) There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 X 5 centimeters.
 - (ii) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.
 - (iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient light, of not less than four (4) in the case of beam limiting devices designed for use with stationary equipment, and a contrast ratio, corrected for ambient light, of not less than three (3) in the case of beam limiting devices designed for use with mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination three (3) millimeters from the edge of the light field toward the center of the light field; and I_2 is the illumination three (3) millimeters from the edge of the light field away from the center of the light field. Compliance shall be determined with a measuring instrument aperture of one (1) millimeter in diameter.
- (5) **Beam Limitation for Portable X-ray Systems.** Beam limitation for portable x-ray

systems shall meet the beam limitation requirements of **Sections E.6(a)(1)** and **Sections E.6(f)(4)**.

- (6) **Field Limitation and Alignment on Stationary General Purpose X-ray Systems.** For stationary, general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with **21 CFR 1020.30(c)**:
- (i) Means shall be provided for positive beam limitation (PBL) which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within five (5) seconds after the insertion of the image receptor, or if adjustment is accomplished in a time interval greater than five (5) seconds, or if manual, will prevent production of x-rays until such adjustment is completed. For the SID at which the device is not intended to operate, the device shall prevent the production of x-rays.
 - (ii) The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than three (3) percent of the SID and that the sum of the length and the width differences without regard to sign be no greater than four (4) percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.
 - (iii) The radiographic system shall be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at 100 centimeters shall be equal to or less than 5 X 5 square centimeters. Return to positive beam limitation as specified in **Section E.6(f)(6)(i)** and **(ii)** shall occur upon change in image receptor.
 - (iv) PBL may be bypassed when radiography is conducted which does not use the cassette tray or permanently mounted vertical cassette holder, or whenever the beam axis or table angulation is not within ten (10) degrees of the horizontal or vertical during any part of the exposure, or during stereoscopic radiography. If the bypass mode is provided, return to positive beam limitation shall be automatic.
 - (v) A capability may be provided for overriding positive beam limitation in the event of system failure or to perform special procedures which cannot be performed in the positive mode. If so provided, a key shall be provided to override the positive mode. It shall be impossible to remove the key while the positive mode is overridden.
- (7) **Timers.** Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting of "zero."
- (8) **Transmission Limits for Image Receptor Supporting Devices Used for Mammography.** For x-ray systems manufactured after September 5, 1978, which are only designed for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure five (5) centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgens for each activation of the tube. Exposure shall be made with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of the tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

(g) **Structural Shielding.**

- (1) All wall, ceiling and floor areas shall be provided with applicable protective barriers as required to assure compliance with **Sections B.14 and Part C** of these regulations. All wall, floor and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in the walls shall extend to a minimum height of eighty-four (84) inches above the floor.
- (2) Secondary barriers shall be provided in all wall, floor and ceiling areas not having primary barriers, or when the primary barrier requirements are lower than the secondary barrier requirements.
- (3) The operator's station at the control shall be behind a protective barrier, either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any ionizing radiation which has been scattered only once. The minimum requirements for the operator's booth are set forth in **APPENDIX C to Part B**.
- (4) A window of lead equivalent glass equal to that required by the adjacent barrier, or a mirror system shall be provided and be large enough and so placed that the operator can see the patient without having to leave the protected area during the exposure.
- (5) Provisions shall be made for the operator to communicate with the patient from a shielded position at the control panel.

(h) **Operating Procedures.**

- (1) No individual exposed to ionizing radiation shall hold patients during exposures except for emergencies, nor shall any individual be regularly used for this service. If a patient must be held, individuals holding the patient shall be protected with appropriate shielding devices such as protective gloves and aprons, and shall be so positioned that no part of their body will be struck by the useful beam.
- (2) The useful beam shall be restricted to the area of clinical interest.

Section E.7: (reserved).

Section E.8: Intraoral Dental Radiographic Installations Systems.

In addition to the provisions of **Section E.3** and **Section E.4**, the requirements of **Section E.8** apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in **Section E.6**.

(a) **Equipment.**

- (1) The tube housing shall be of diagnostic type.
- (2) Each installation shall be provided with a protective barrier for the operator, or shall be so arranged that the operator can stand at least six (6) feet from the patient, well away from the useful beam.

(b) **Source-to-Skin Distance (SSD).** x-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the SSD to not less than:

- (1) 18 centimeters if operable above 50 kVp; or,
- (2) 10 centimeters if not operable above 50 kVp.

(c) **Field Limitation.**

- (1) Radiographic devices designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:
 - (i) If the minimum SSD is eighteen (18) centimeters or more, the x-ray field at the minimum SSD shall be contained in a circle having a diameter of no more than seven (7) centimeters; and
 - (ii) If the minimum SSD is less than eighteen (18) centimeters, the x-ray field at the minimum SSD shall be contained in a circle having a diameter of no more than six (6) centimeters.
- (2) An open ended, shielded positive indicating device shall be used. The shielding in such a device shall be equivalent to that required in Section E.4(c).

(d) **Timers.** Means shall be provided to terminate the exposure at a preset time interval, preset product of time and current, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

- (1) 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.
- (2) **Reproducibility.** With a timer setting of 0.5 second or less, the average exposure period (T_{avg}) shall be greater than or equal to five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) where four timer tests are performed:

$$T_{avg} \geq 5(T_{max} - T_{min}).$$

(e) **x-ray Control.**

- (1) 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 0.5 second or less.
- (2) Each x-ray control shall be located in such a way as to meet the following requirements:
 - (i) Stationary x-ray equipment shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and
 - (ii) Mobile and portable x-ray systems which are:
 - (a) Used for greater than one (1) week in the same location (i.e., a room or suite) shall meet the requirements of **Section E.8(e)(2)(i)**;
 - (b) Used for greater than one (1) hour and less than one (1) week in the same location (i.e., a room or suite) shall meet the requirements of **Section E.8(e)(2)(ii)(a)** or be provided with a 6.5 feet (1.98 m) high protective barrier which is placed at least six (6) feet (1.83 m) from the tube housing assembly and at least six (6) feet (1.83 m) from the patient; or
 - (c) Used to make an exposure(s) of the patient at the use location shall meet the requirements of **Section E.8(e)(2)(ii)(a)** or **(b)** or be provided with a method of x-ray control which will permit the operator to be at least twelve (12) feet (3.66 m) from the tube housing assembly during an exposure.

(3) 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 been terminated.

- (f) **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 (4) exposures are made at identical technique factors, the value of the average exposure (E_{avg}) is greater than or equal to five (5) times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$E_{avg} \geq 5(E_{max} - E_{min}).$$

- (g) **Structural Shielding.**

- (1) All wall, ceiling and floor areas shall be provided with applicable protective barriers as required to assure compliance with **Sections B.14 and Part C** of these regulations.
- (2) When dental x-ray units are installed, the rooms adjacent to the installed units shall be adequately protected.

- (h) **Administrative Controls.**

- (1) Neither the dentist nor his assistant(s) shall be permitted to hold the patient or the film during exposures, nor shall any other individual be used regularly for this purpose. Patient and film holding devices shall be used when technique permits.
- (2) During each exposure the operator shall stand at least six (6) feet from the patient or behind a protective barrier.
- (3) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of **Section E.8(c)(1)**.
- (4) Neither the tube housing nor the positive indicating device shall be hand held during an exposure.
- (5) Dental fluoroscopy without image intensification shall not be used in dental examinations.

- (i) **Additional Requirements Applicable to Certified Systems Only.** Only diagnostic x-ray systems incorporating one or more certified components shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

- (1) **Reproducibility.** When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, the estimated coefficient of variation of radiation exposure shall be no greater than 0.05, for any specific combination of selected technique factors.
- (2) **Linearity.** When the equipment allows a choice of x-ray tube current settings and is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential in the range of 40 to 100 percent of the maximum rating, the average ratio of exposure to the indicated milliamperere seconds product obtained by any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|\frac{X_{avg1} - X_{avg2}}{X_{avg1} + X_{avg2}}| \leq 0.10$$

- (3) **Accuracy.** Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
- (4) **Timers.** Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."
- (5) **Beam Quality.** All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer of not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the requirements of **Section E.4(e)(1)**.

SECTION E.9: Therapeutic X-ray Installations.

(a) Equipment.

- (1) The tube housing shall be of therapeutic type.
- (2) Permanent diaphragms or cones used for collimating the useful beam shall afford the same degree of protection as the tube housing. Adjustable or removable beam-defining diaphragms or cones shall transmit not more than five (5) percent of the useful beam obtained at the maximum kilovoltage and with maximum treatment filter.
- (3) Filters shall be secured in place to prevent them from dropping out during treatment. The filter slot shall be so constructed that the ionizing radiation escaping through it does not exceed one (1) roentgen per hour at one (1) meter; or, if the ionizing radiation from the slot is accessible to the patient, thirty (30) roentgens per hour at five (5) centimeters from the external opening.
- (4) The x-ray tube shall be so mounted that it can not turn or slide with respect to the aperture.
- (5) Means shall be provided to immobilize the tube housing during stationary portal treatment.
- (6) A timer shall be provided to terminate the exposure after a preset time regardless of what other exposure limiting devices are present.
- (7) Equipment utilizing shutters to control the useful beam shall have a shutter position indicator on the control.
- (8) There shall be on the control panel an easily discernible indicator which will give positive information as to whether or not the x-ray tube is energized.

(b) Structural Shielding.

- (1) All wall, ceiling and floor areas shall be provided with applicable protective barriers as required to assure compliance with **Sections B.14 and Part C** of these regulations. All wall, floor and ceiling areas that can be struck by the useful beam plus a border of one (1) foot shall be provided with primary protective barriers.
- (2) All wall, floor and ceiling areas that can not be struck by the useful beam shall be provided with secondary protective barriers.
- (3) With equipment operating above one hundred twenty-five (125) kVp, the required barrier shall be an integral part of the building.

- (4) With equipment operating above one hundred fifty (150) kVp, the control panel shall be within a protective booth equipped with an interlock door, or outside of the treatment room.
- (5) Interlocks shall be provided for x-ray therapy equipment capable of operating above one hundred fifty (150) kVp so that when any door of the treatment room is opened, either the machine will shut off automatically or the ionizing radiation level within the room will be reduced to an average of not more than two (2) milliroentgens per hour and a maximum of ten (10) milliroentgens per hour at a distance of one (1) meter in any direction from the target. After such reduction in output, it shall be possible to restore the machine to full operation only from the control panel.
- (6) Provisions shall be made to permit continuous observation of and communication with the patients during irradiation.
- (7) Windows, mirror systems, or closed circuit television viewing screens used for observing the patient shall be so located that the operator can see the patient and the control panel from the same position.

(c) **Operating Procedures.**

- (1) All new installations shall have protective surveys made by the Department or under the direction of a qualified expert. This shall also be done after any change in the installation which might produce a radiation hazard. If the survey is done by someone other than the Department, the expert shall report his findings in writing to the person in charge of the installation and to the Department.
- (2) The installation shall be operated in compliance with any limitations indicated by the protective survey.
- (3) No individual who works with ionizing radiation, unless he is the patient, shall be in the treatment room during exposures. No other individual shall be there except when it is clinically necessary. If any individual is required to be in the treatment room with the patient during exposure, he shall be protected as much as possible from scattered ionizing radiation and shall not be in the useful beam.

(d) **Calibration of X-ray Therapy Equipment.** The output of each therapeutic x-ray machine shall be calibrated by or under the direction of a qualified expert. The calibration shall be repeated after any change in or replacement of components of the x-ray generating equipment which could cause a change in the x-ray output. Check calibrations shall be made at least once a year thereafter. Records of the calibrations shall be maintained by the registrant.

(e) All requirements of this Section apply to therapeutic veterinary installations.

Section E.10: X-ray Therapy Equipment Operated at Potentials of Sixty (60) kV and Below.

(a) **Equipment.**

- (1) All provisions of **Section E.9(a)** apply except for equipment used for "contact therapy," **Section E.9(a)(1)**, in which instance the leakage radiation at the surface of the tube housing shall not exceed 0.1 roentgen per hour.
- (2) There shall be on the control panel some easily discernible device which shall give positive information as to whether or not the tube housing is energized.

(b) Operating Procedures.

- (1) Automatic timers shall be provided which shall permit accurate presetting and determination of exposures as short as one (1) second.
- (2) In the therapeutic application of an apparatus constructed with beryllium or other low-filtration windows, the registrant shall ensure that the un-filtered radiation reaches only the part intended and that the useful beam is blocked at all times except when actually being used.
- (3) Machines having an output of more than 1000 roentgens per minute at any accessible place shall not be left unattended without the power being shut off at the primary disconnecting means.

Section E.11: Veterinary Medicine Radiographic Installations.**(a) Equipment.**

- (1) The protective tube housing shall be of diagnostic type equivalent to the requirements of **Section E.4(c)**.
- (2) 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 tube housing as indicated in **Section E.6(a)(2)**.
- (3) Except as contraindicated for a particular radiographic purpose, the total filtration permanently in the useful beam shall not be less than 0.5 millimeter aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeter aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeter aluminum equivalent for machines above 70 kVp.
- (4) A device shall be provided to terminate the exposure at a preset time interval, preset product of time and current, a preset number of pulses, or a preset radiation exposure to the image receptor.
- (5) A dead-man type 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 six (6) feet (1.83 m) from the animal during all x-ray exposures.

(b) Structural Shielding. All wall, ceiling and floor areas shall be provided with applicable protective barriers as required to assure compliance with **Sections B.14 and Part C** of these regulations.

(c) Operating Procedures.

- (1) The operator shall stand well away from the useful beam and the animal during radiographic exposures. Provisions shall be made so that it will not be necessary for the operator to stand in the useful beam. Hand held fluoroscopic screen shall not be used. The tube housing assembly shall not be held by the operator. No individual other than the persons involved in the operation shall be in the x-ray room while exposures are being made unless such individual's assistance is required.
- (2) In any operation in which the operator or the assistant is not located behind a protective barrier, a protective apron and gloves having lead equivalence of not less than 0.5 millimeter shall be worn.

- (3) When an animal must be held in position during radiography, mechanical supporting devices or restraining devices 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 having lead equivalents of not less than 0.5 millimeter, and shall be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

Author: James D. Archer, Jr., Environmental Health Program Supervisor.

Authority: §§; 22-2-1, 22-2-2, 22-2-5, and 22-2-6; and 22-3-4; also 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, Code of Alabama, 1975.

History: Promulgated Jan. 1, 1961; revised Sept. 1, 1969; Nov. 1, 1971; revised Oct. 1, 1977; revised June 10, 1981; revised Aug. 12, 1986; revised NOV. 9, 1994.

APPENDIX A

REQUEST FOR THE USE OF X-RAYS FOR HEALING ARTS SCREENING

- 1. Reg. No:|__| 37 - |__|__|__| 3. Applicant:|_____|
- 2. Date:|__|__| - |__|__| - |__|__| 4. Street Addr:|_____|
- 5. City:|_____| 6. State:|__|__| 7. Zipcode:|__|__|__|__|__|
- 8. Physicians reading Films: |_____|
|_____|
- 9. Alabama physician(s) authorizing screening:|_____|

10. Authorizing physician's statement as to why such screening is required for the group(s) to be x - rayed. This statement should include appropriate literature, references, any morbidity rates, and other pertinent data justifying the need for such procedure(s). (use additional pages if necessary)

11. Group(s) of individuals to be x - rayed (include locations and estimated dates procedures will be performed). (use additional pages if necessary)

12 Signed : _____ Dated : |__|__| - |__|__| - |__|__|

13. This request will be referred to the Jefferson County Board of Health. You will receive a copy when your project is approved or disapproved. If rejected, you have the right of appeal and should contact this Department for details.

Approved : _____ Dated : |__|__| - |__|__| - |__|__|
Carol W. Samuelson, M.D.
Health Officer

Disapproved : _____ Dated : |__|__| - |__|__| - |__|__|
Carol W. Samuelson, M.D.
Health Officer

PART F

NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS

Section F.1: Purpose and Scope.

This Part establishes the requirements for notices, instructions and reports by registrants to individuals in registered activities and options available to such individuals in connection with Department inspections of registrants to ascertain compliance with the provisions of the Act and regulations and orders issued thereunder regarding radiological working conditions. The regulations in this Part apply to all persons who receive, possess, use, own, or transfer sources registered with the Department pursuant to these regulations.

Section F.2: Posting Of Notices To Workers.

Each registrant shall post current copies of the following documents:

- (a) **Regulations and Procedures.** Each registrant shall post current copies of the following documents:
 - (1) Regulations in this Part and **Part C**;
 - (2) The Notice of Registration;
 - (3) The operating procedures applicable to work under the registration; and
 - (4) Any notice of violation involving radiological working conditions or orders issued under **Part B**, and any response from the registrant.
- (b) If the posting of a document specified in **Section F.2: (a)(1), (2), (3) or (4)** is not practicable, the registrant may post a notice which describes the document and states where it may be examined.
- (c) Department **Form "X" - "NOTICE TO EMPLOYEES"** - shall be posted by each registrant wherever individuals work in or frequent any portion of a restricted area.
- (d) Notices of violations involving radiological working conditions:
 - (1) Department documents posted pursuant to **Section F.2(a)(4)** shall be posted within two (2) working days after receipt of the document from the Department.
 - (2) The registrant response, if any, shall be posted within two (2) working days after dispatch from the registrant.
 - (3) Such documents shall remain posted for a minimum of five (5) working days or until action correcting the violation(s) has been completed.
- (e) Documentation's, notices or forms posted pursuant to this Section shall:
 - (1) Appear in sufficient number of places to permit individuals engaged in work under the registration to observe them on the way to or from any particular work location to which the document applies;

- (2) Be conspicuous; and
- (3) Be replaced if defaced or altered.

Section F.3: Instructions To Workers.

All individuals working in or frequenting any portion of a restricted area shall be:

- (a) Kept informed of the storage, transfer, or use of radiation in such portions of the restricted area;
- (b) Instructed in the health protection problems associated with exposure to such radiation;
- (c) Instructed in, and instructed to observe, to the extent within the worker's control, precautions and procedures to minimize exposure, and instructed in the purpose and function of protective devices employed for the protection of personnel from exposure to radiation occurring in such areas;
- (d) Instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of Department rules for the protection of personnel from exposure to radiation occurring in such areas;
- (e) Instructed of their responsibility to report to the registrant any conditions which may lead to or cause a violation of the Department's regulations or unnecessary exposure to radiation;
- (f) Instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation; and
- (g) Advised as to the radiation exposure reports which workers may request pursuant to **Section F.4.**

The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

Section F.4: Notification And Reports To Individuals.

- (a) Radiation exposure data for an individual and the results of any measurement and analysis shall be reported to the individual as specified in this Section. The information reported shall include data and results obtained pursuant to the Department regulations, or orders as shown in records maintained by the registrant pursuant to Department regulations. Each notification and report shall be in writing and shall include appropriate identifying data such as the:
 - (1) Name of the registrant;
 - (2) Name of the individual;
 - (3) Individual's Social Security Number; and
 - (4) Individual's exposure information.

And include the following statement: "This report is furnished to you under the provisions of the Jefferson County Department of Health Regulations entitled, 'Regulations to Govern the Production and Use of Radiation.' You should preserve this report for future reference."

- (b) At the request of any worker, each registrant shall advise such worker annually of the worker's exposure to radiation as shown in the records maintained by the registrant pursuant to **Part C**.
- (c) At the request of a worker formerly engaged in work controlled by the registrant, each registrant shall furnish to the worker a report of the worker's exposure to radiation. Such report shall:
 - (1) Be furnished within thirty (30) days of the time the report is made, or within thirty (30) days after the exposure of the individual has been determined by the registrant, whichever is later;
 - (2) Cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure from radiation machines registered with the Department; and
 - (3) Include the dates and locations of work under the registration in which the worker participated during this period.
- (d) When a registrant is required pursuant to **Part C** to report to the Department any exposure of an individual to radiation, the registrant shall also provide the individual with a report on his exposure data included therein. Such report shall be transmitted at a time not later than the transmittal to the Department.
- (e) At the request of a worker who is terminating employment in a given calendar quarter with the registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the registrant's facility in that calendar quarter, each registrant shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the registrant during that specifically identified calendar quarter or fraction thereof, or provide a written statement of that dose if the finally determined personnel monitoring results are not available at that time.

Author: James D. Archer, Jr., Environmental Health Program Supervisor.

Authority: §§; 22-2-1, 22-2-2, 22-2-5, and 22-2-6; and 22-3-4; also 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, Code of Alabama, 1975.

History: Promulgated Jan. 1, 1961; revised Sept. 1, 1969; Nov. 1, 1971; revised Oct. 1, 1977; revised June 10, 1981; revised Aug. 12, 1986; revised NOV. 9, 1994.

PART G INSPECTIONS

Section G.1: Presence of Representatives of Registrant and Workers During Inspections.

- (a) Each registrant shall afford to the Department at all reasonable times an opportunity to inspect material, machines, activities, facilities, premises, and records pursuant to these regulations.
- (b) During an inspection, Department inspectors may consult privately with workers as specified in **Section G.2**. The registrant may accompany Department inspectors during other phases of an inspection.
- (c) If at any time of inspection an individual has been authorized by the workers to represent them during Department inspections, the registrant shall notify the inspector of such authorization and shall give the workers' representative an opportunity to accompany the inspector during the inspection of physical working conditions.
- (d) Each workers' representative shall be routinely engaged in work under control of the registrant and shall receive instructions as specified in **Section F.3**.
- (e) Different representatives of registrants and workers may accompany the inspector during different phases of the inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspector.
- (f) With the approval of the registrant and the workers' representative, an individual who is not routinely engaged in work under control of the registrant, (e.g., a consultant to the registrant or the workers' representative), shall be afforded the opportunity to accompany the Department inspector(s) during the inspection of physical working conditions.
- (g) Notwithstanding the other provisions of this Section, Department inspectors are authorized to refuse to permit accompaniment by any person 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 registrant to enter that area.

Section G.2: Consultations with Workers During Inspections.

- (a) Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Department regulations 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 inspector, 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 or any unnecessary exposure of an individual to radiation from all sources of radiation under the registrants control. Any such notice in writing shall comply with the requirements of **Section G.3**.
- (c) The provisions of **Section G.2(b)** shall not be interpreted as authorization to disregard instructions pursuant to **Section G.3**.

Section G.3: Request by Workers for Inspection.

- (a) Any worker or representative of workers, who believes that a violation of the Act or these regulations exists or has occurred in work under a 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 Department. 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 registrant by the Department no later than at the time of inspection except that, upon request of the worker giving such notice, his name and the names of the individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Department, except for good cause shown.
- (b) If upon receipt of such notice the County Health Officer or the Director of the Division of Radiological Health determines that the complaint meets the requirements set forth in **Section G.3(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.
- (c) No 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 proceedings under these regulations, or has testified or is about to testify in any such proceedings, or because of the exercise by such worker on the behalf of himself or others of any option afforded by this Part.

Section G.4: Inspections Not Warranted; Informal Review.

- (a) If the Division Head of Radiological Health determines, with respect to a complaint under **Section G.3**, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, he shall notify the complainant in writing of such determination. The complainant may obtain a review of such determination by submitting a written statement of position with the County Health Officer who will provide the registrant with a copy of such statement by certified mail, excluding at the request of the complainant, the name of the complainant. The registrant may submit an opposing written statement of position with the County Health Officer who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the County Health Officer may hold an informal conference in which the complainant and the registrant may orally present their views. An informal conference may also be held at the request of the registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization of the complainant.

After considering all written or oral views presented, the Health Officer shall affirm, modify, or reverse the determination of the Division of Radiological Health and furnish the complainant and the registrant a written notification of his/her decision and the reason therefor.

- (b) If the Director of the Division of Radiological Health determines that an inspection is not warranted because the requirements of **Section G.3(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 **Section G.3(a)**.

Author: James D. Archer, Jr., Environmental Health Program Supervisor.

Authority: §§; 22-2-1, 22-2-2, 22-2-5, and 22-2-6; and 22-3-4; also 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, Code of Alabama, 1975.

History: Promulgated Jan. 1, 1961; revised Sept. 1, 1969; Nov. 1, 1971; revised Oct. 1, 1977; revised June 10, 1981;

revised Aug. 12, 1986; revised NOV. 9, 1994.

PART H
RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

Section H.1: Purpose and Scope.

This Part provides special requirements for analytical x-ray equipment; provided, however, that nothing in this Part shall apply to x-ray equipment used to detect, measure, gauge, or control the density, level, interface location, thickness, or equipment used for industrial radiography as defined in **Part D**, or sources of radiation used in the healing arts. The requirements of this Part are in addition to, and not in substitution for, applicable Sections in other Parts of these regulations. Note that **Parts A, B, C, and F** also apply to analytical x-ray equipment users.

Section H.2: Definitions.

Definitions as used in this Part may be found in the Glossary.

Section H.3: Equipment Requirements.

(a) **Safety Devices.** A device such as a guard or an interlock which prevents the entry of any portion of any individual's body into the primary beam path shall be provided on all open beam configurations. Prior to operation, a registrant may apply to the Department for an exemption from the requirements of a safety device. Such application shall include 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.**

(1) A positive visible warning light which shall be illuminated only when the tube is energized, and labeled with the words "**X-RAY ON**" or words having a similar intent shall be located:

- (i) Near any switch that energizes an x-ray tube; and
- (ii) At a conspicuous location that may be visible from all local components.

(2) Open-beam configurations shall be provided with a readily discernible indication of:

- (i) X-ray tube status (**ON-OFF**) located near the radiation source housing, if the primary beam is controlled in this manner; and/or
- (ii) Shutter status (**OPENED-CLOSED**) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

Warning devices shall be clearly labeled so that their purpose is easily identified. On equipment transferred after January 1, 1977, warning devices shall have fail-safe characteristics.

(c) **Labeling.** All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

CAUTION-HIGH INTENSITY X-RAY BEAM

or words having a similar intent on the x-ray source housing, such as:

CAUTION-RADIATION**THIS EQUIPMENT PRODUCES
X-RAYS WHEN ENERGIZED**

or words having a similar intent, near any switch that energizes an x-ray tube, and at a conspicuous location if the radiation source is an x-ray tube.

- (d) **Ports.** 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 shielded coupling has been connected to the port.
- (e) **Radiation Source Housing.** Each x-ray tube shall be so constructed that with all shutters closed the leakage radiation measured at a distance of five (5) centimeters from its surface is not capable of producing a dose in excess of 2.5 mrem in one (1) hour at any specified tube rating.
- (f) **Generator Cabinet.** Each x-ray generator, including high voltage rectifiers, transformers, and amplifiers, shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five (5) centimeters from the surface such that it is not capable of producing a dose in excess of 0.25 mrem in one (1) hour.
- (g) **Unattended Operation.** Each entrance to a room containing analytical x-ray equipment in an unattended operation shall have a warning light with the words "**X-RAY ON**" or words having a similar intent. In addition, for an open beam configuration unattended operation, there shall be a device to shut off the analytical x-ray equipment upon the entrance of any person not trained in accordance with **Section H.6** of this Part.

Section H.4: Area Requirements.

- (a) **Radiation Levels.** The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation level exists 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 **Part C** of these regulations. These levels shall be met at any specified tube rating.
- (b) **Surveys.** Radiation surveys with appropriate radiation detection devices, as required by **Part C**, of all operable analytical x-ray systems sufficient to show compliance with **Section H.4(a)** shall be performed quarterly and:
 - (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;
 - (4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary beam when any local component in the system is disassembled or removed;
 - (5) Any time a visual inspection of the local components in the system reveals an abnormal condition; and

- (6) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in **Part C**.
- (c) **Posting.** Each area or room containing analytical 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.

Section H.5: Operating Requirements.

- (a) **Procedures.** Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the individual designated to the Department as the Radiation Safety Officer.
- (b) **Bypassing.** No person shall bypass the safety device unless such person has obtained the written approval of the individual designated as 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.

Section H.6: Personnel Requirements.

- (a) **Instruction.** No person shall be permitted to operate or maintain analytical 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, or the reason they have not been installed on certain pieces of equipment, and the extra precautions required in such case;
 - (3) Proper operating procedures for the equipment;
 - (4) Biological effects of radiation, including symptoms of acute localized exposure; and
 - (5) Proper procedures for reporting an actual or suspected exposure.
- (b) **Personnel Monitoring.** Finger or wrist dosimetric devices shall be provided to and shall be used by:
- (1) Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
 - (2) Personnel maintaining analytical x-ray equipment, if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

In reporting dose values, due consideration should be given to the energy of the x-ray beam and the size of the x-ray beam.

Author: James Archer, Environmental Health Program Supervisor.

Authority: §§; 22-2-1, 22-2-2, 22-2-5, and 22-2-6; and 22-3-4; also 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, Code of Alabama, 1975.

History: Promulgated Jan. 1, 1961; revised Sept. 1, 1969; revised Nov. 1, 1971; revised Oct. 1, 1977; revised June 10, 1981; revised Aug. 12, 1986; revised NOV. 9, 1994.

PART I
Tanning Facilities

Section I.1: Authority, Purpose, and Scope.

- (a) The Jefferson County Board of Health is authorized to promulgate this part under and by virtue of **Act No. 94-619, Alabama Legislature, Regular Session 1994.**
- (b) This Part provides for the registration of tanning facilities using ultraviolet lamps, and regulation of the maintenance and operation of tanning facilities.
- (c) In addition to the requirements of this Part, all facilities are subject to the applicable provisions of other Parts of these regulations.
- (d) Nothing in this Part shall be interpreted as limiting the intentional exposure of patients to ultraviolet radiation for the purpose of treatment or use commensurate with the licensed practitioner's use of a healing art.

Section I.2: Definitions.

General definitions are found in the glossary, the following terms are defined for purposes of this Part:

Act - means **Act No. 94-619, Alabama Legislature, Regular Session 1994.**

CFR - means Code of Federal Regulations.

Consumer - means any member of the public who is provided access to a tanning facility in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning facility as a condition or benefit of membership or access.

Department - means the Jefferson County Board of Health.

FDA - means Federal Food and Drug Administration.

Installer - means an individual who installs tanning devices.

Operator - means an individual designated by the permittee to control operation of the tanning facility and to instruct and assist the consumer in the proper operation of the tanning device.

Permit - means a permit issued by the Department in accordance with regulations promulgated by the Department.

Permittee - means any person who obtains a permit or other entitlement from the Department, and who is obligated to obtain such permit or other entitlement from the Department pursuant to these regulations and the Act.

Radiation machine - means any device capable of producing ultraviolet radiation.

Radiation - means ultraviolet radiation.

Service agent - means any person engaged in the business of assembling, replacing, or installing tanning devices into tanning facilities, or are in the business of providing services and

products to tanning facilities. The term includes the owner of the tanning facility, his or her employee or agent, who installs tanning devices that are subsequently used to provide professional or commercial services.

Tanning device - means equipment that emits electromagnetic radiation of wavelengths between 200 and 400 nanometers and is used for tanning the skin, including, but not limited to, a sunlamp, tanning booth, tanning bed, or any accompanying equipment.

Tanning facility - means any location, place, area, structure or business that provides to its customers access to a tanning device.

This Part - means "**Part I**" of these Regulations.

Ultraviolet radiation - means electromagnetic radiation with wavelengths in air between two hundred (200) nanometers and four hundred (400) nanometers.

Section I.3: Exemptions.

- (a) **General.** The Department may, in its sole discretion, 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.
- (b) Equipment intended for purposes other than the deliberate exposure of parts of the living human body to ultraviolet radiation, and which produce or emit ultraviolet radiation incidental to its proper operation are exempt from the provisions of this Part.
- (c) Tanning devices while in transit or storage incidental thereto are exempt from provisions of this Part. Tanning devices in storage shall be rendered inoperable by disconnecting the power cord.

Section I.4: Application for Permitting Of Tanning Facilities.

- (a) Every person who operates a tanning facility shall apply for a permit for each tanning device with the Department within thirty (30) days following the effective date of this Part or thereafter prior to the operation of a tanning facility. Application for a permit shall be completed on a form satisfactory to the Department and shall contain all the information required by the form and any accompanying instructions.
- (b) The applicant shall complete at least the following information on the application form:
 - (1) Name, address and telephone number of the following:
 - (i) The tanning facility; and
 - (ii) The owner(s) of the tanning facility.
 - (2) The manufacturer, model number, and type of each ultraviolet lamp or tanning equipment located within the facility.
 - (3) The geographic areas within Jefferson County to be covered, if the facility is mobile.
 - (4) Name of the tanning equipment supplier, installer, and service agent.
 - (5) A signed and dated certification that the applicant has read and understands the requirements of these Regulations.

- (6) A copy of operating and safety procedures unique to facility operation.
- (c) Each applicant shall provide any additional information as the Department may require.

Section I.5: Issuance of Permit.

- (a) Upon determination that an applicant meets the requirements of **Section I.4**, the Department shall issue a permit.
- (b) The Department may incorporate in the permit at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the permittee's receipt, possession, use and transfer of tanning facilities as it deems appropriate or necessary.
- (c) No person shall operate a tanning facility until the Department has issued the permit.

Section I.6: Expiration of Permit.

Except as provided in **Section I.7(b)**, each permit shall expire on the thirty-first day of March each year.

Section I.7: Renewal of Permit.

- (a) Application for renewal of permit shall be filed in accordance with **Section I.4**.
- (b) In any case in which a permittee not less than thirty (30) days prior to the expiration of his existing permit has filed an application in proper form for renewal, such existing permit shall not expire until the status of the renewal of the permit has been finally determined by the Department.

Section I.8: Report of Changes.

The permittee shall notify the Department in writing before making any change which would render the information contained in the application, reported pursuant to **Sections I.4(b)(i), (ii), (iii), and (vi)** for the permit application no longer accurate. This requirement shall not apply to changes involving replacement of designated original equipment lamp types with lamps which have been certified with the FDA as "equivalent" lamps under the FDA regulations and policies applicable at the time of replacement of the lamps. The permittee shall maintain manufacturer's literature demonstrating the equivalency of any replacement lamps.

Section I.9: Transfer of Permit.

No permit shall be transferable from one person to another or from one tanning facility to another.

Section I.10: Approval Not Implied.

No person, in any advertisement, shall refer to the fact that he or his facility is permitted by the Department pursuant to the provisions of Section I.4, and no person shall state or imply that any activity under such permit has been approved by the Department.

Section I.11: Denial, Suspension, or Revocation of Permit.

- (a) The Department may, for good cause shown, deny, suspend or revoke a permit sought or issued pursuant to these regulations for any of the following reasons:

- (1) Failure of reports, plans or specifications to show that the tanning facility will be constructed, operated, or maintained in accordance with the requirements of these regulations;
 - (2) Submission of incorrect, false or misleading information in the application, reports, plans, or specifications;
 - (3) Failure to construct, operate or maintain the tanning facility in accordance with the application, plans and specifications approved by the Department except as such maintenance may involve the replacement of lamps by "equivalent" lamps which have been defined in **Section I.8** above;
 - (4) Operation of the tanning facility in a way that causes or creates a nuisance or hazard to the public health or safety;
 - (5) Violation of any rules, regulations, standards, or requirements adopted by the Department;
 - (6) Violation of any condition upon which the permit was issued;
 - (7) Failure to allow duly authorized agents of the Department to conduct inspections at reasonable hours and in a reasonable manner; and
 - (8) Failure to pay permit fees.
- (b) **Hearing.** If any permit is denied, suspended, or revoked, the applicant or owner may, within seven (7) days following receipt of said notice, apply in writing for a hearing to the Health Officer or his/her designee. The Health Officer shall fix the time and place for such hearing. Following such a hearing the decision of the Health Officer shall be final.

Section I.12: Construction and Operation of Tanning Facilities.

Unless otherwise ordered or approved by the Department, each tanning facility shall be constructed, operated, and maintained to meet the following minimum requirements:

(a) Physical Facilities.

- (1) The warning sign, as shown in **Appendix A** to this Part, shall be posted in the immediate proximity (within 1 meter) of each piece of tanning equipment. It shall be readily legible, clearly visible, and not obstructed by any barrier, equipment, or other item present so that the user can easily view the warning sign before energizing the ultraviolet light generating equipment. The lettering on each warning sign shall be at least ten (10) millimeters high for all words shown in capital letters and at least five (5) millimeters high for all lower case letters.
- (2) Only tanning devices manufactured and certified to comply with **21 CFR Part 1040, Section 1040.20** "Sunlamp products and ultraviolet lamps intended for use in sunlamp products", shall be used in tanning facilities. Compliance shall be based on the standard in effect at the time of manufacture as shown on the device identification label required by **21 CFR Part 1010, Section 1010.3**.
- (3) The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time. Each tanning device shall use a timer which is accurate for any and all selected time intervals to plus or minus 10 percent of the actual timer setting. In addition, all timers shall comply with the requirements of **21 CFR Part 1040, Section 1040.20(c)(2)**.

- (4) Tanning devices shall meet the National Fire Protection Association's National Electrical Code.
 - (5) Tanning devices shall be equipped with physical barriers to protect consumers from injury induced by touching or breaking the lamps.
 - (6) Additional requirements for stand-up booths:
 - (i) There shall be physical barriers or other means such as handrails or floor markings to indicate the proper exposure distance between ultraviolet lamps and the consumer's skin.
 - (ii) The construction of the booth shall be such that it will withstand the stress of use and the impact of a falling person.
 - (iii) Access to the booth shall be of rigid construction.
 - (iv) Doors shall open outwardly.
 - (v) Handrails and nonslip floors shall be provided.
 - (7) **Health and Safety Standards.** Tanning devices and the area shall be constructed so as to allow proper cleaning and sanitation between uses by consumers.
 - (8) **Construction Requirements.** Rooms for tanning devices shall meet the minimum design requirements of **Appendix B** to this Part.
 - (9) **Towels.** Individual towels shall be provided in rooms with tanning devices and shall have been laundered by an approved method since last used. Towels, whenever provided in rooms with tanning devices, public wash rooms or baths, shall be individual towels and if of cloth, shall have been laundered since last used.
 - (10) **Bathhouses.** Bathhouses where provided shall be kept clean and in good repair, and shall provide adequate dressing and plumbing facilities for each sex. The room should be well lighted, drained, ventilated, and of good construction with impervious materials employed in general and so developed and planned that good sanitation can be maintained.
 - (11) **Toilet and Lavatory facilities.** Toilet and lavatory facilities shall be installed according to law and shall be located to allow convenient use by consumers and employees. Toilet and lavatory fixtures shall be clean and be kept in good repair. A supply of toilet tissue shall be kept at each toilet at all times. Easily cleanable receptacles shall be provided for waste materials. Toilet rooms used by women should have at least one covered waste receptacle.
- (b) **Protective Goggles.**
- (1) Each consumer shall be provided with protective goggles and instructions for proper use.
 - (2) Protective goggles shall meet the requirements of **21 CFR Part 1040, Section 1040.20(c)(5)**.
 - (3) Protective goggles shall be properly sanitized before each use. Exposure to the ultraviolet radiation produced by the tanning equipment itself is not considered a sanitizing agent.

(4) Each consumer shall wear protective goggles as instructed.

(c) **Operation.**

- (1) An operator shall be present when tanning equipment is operated.
- (2) Prior to initial exposure each customer shall be provided the opportunity to read a copy of the warning specified in **Section I.12(a)(i)**. The operator shall then request that the consumer sign a statement that the information has been read and understood. For illiterate or visually handicapped persons, the warning statement shall be read by the operator in the presence of a witness. Both the witness and the operator shall sign the statement.
- (3) A record shall be kept by the facility operator of each consumer's total number of tanning visits and tanning exposure times.
- (4) A written report of any tanning injury shall be forwarded to the Department within two (2) working days of the occurrence or knowledge thereof. See **Appendix C** to this part for an example of the Report of Injury Form. The report shall contain at least the following:
 - (i) the name of the affected individual;
 - (ii) the name and location of the tanning facility involved;
 - (iii) the nature of the injury;
 - (iv) name and address of health care provider, if any; and
 - (v) any other information considered relevant to the situation.

(5) **Use by Minors.**

A minor between the ages of 14 and 17 shall not be able to use a tanning device, unless the facility has on file a statement signed by the parent or legal guardian of the minor stating that the parent or legal guardian has read and understands all warnings the tanning facility is required to post, consents to the minor using the tanning device, and agrees that the minor will use the provided protective eyewear. A minor under the age of 14 shall be accompanied by a parent or legal guardian on the minor's initial visit and the parent or legal guardian shall give written permission for the minor to use a tanning device. The parent or guardian shall be provided, by the operator, with the basic information required under **Section I.12(a)(i)**.

- (6) Defective or burned-out lamps or filters shall be replaced with a type intended for use in that device as specified on the product label on the tanning equipment, or, with lamps or filters that are "equivalent" under the FDA regulations and policies applicable at the time of lamp manufacture.
- (7) Each operator shall be adequately trained. Proof of training for each operator shall be maintained on file in the facility and available for inspection by the Department upon request. Training shall include:
 - (i) The requirements of these Regulations;
 - (ii) Procedures for correct operation of the facility;
 - (iii) Recognition of injury or overexposure;

- (iv) Manufacturer's procedures for operation and maintenance of tanning equipment; and
- (v) Emergency procedures in case of injury.

Section I.13: Enforcement and Penalties.

- (a) The Department may impose an administrative fine in an amount not to exceed one hundred dollars (\$100.00) per day for any violation of the Act, any regulation adopted pursuant to the Act, or any term or condition of any permit issued by the Department. The imposition of an administrative fine shall not preclude the Department seeking other remedies, including, but not limited to, injunctive relief or the imposition of civil penalties as provided by the Act. The total administrative fine shall not exceed one thousand five hundred dollars (\$1,500).
- (b) In determining the amount of fine to be levied for a violation, as provided in **Section I.13(a)**, each of the following factors shall be considered:
 - (1) The extent and severity of any violation of the Act, or the regulations adopted pursuant to this act.
 - (2) Actions taken by the permittee to correct the violation.
 - (3) Any previous violations by the permittee.
- (c) The Department may institute legal action for injunctive or other relief to enforce this act.

Section I.14: Inspections.

- (a) Inspections shall be conducted as prescribed in **Part G** of these regulations.
- (b) **Posting of Inspection Results.** Each permittee shall post current copies of the inspection report, and any notices of violation involving conditions or orders issued under this Part. Posting shall be in a location easily visible to the consumer.

Section I.15: Severability.

If any provision, clause, section, sentence or paragraph of this Part or the application thereof to any person shall be held to be invalid, such invalidity shall not affect the remaining provisions or applications of the regulations. The valid portion of any provision, clause, section, sentence or paragraph shall be given independence from the invalid provisions or applications, and to this end this Part are hereby declared to be severable.

Section I.16: Effective Date.

This Part shall have an effective date established by its promulgation by the Jefferson County Board of Health.

Authors: James Carroll, Director of Environmental Health; Frank Philips, Assistant Director of Environmental Health; and, James Archer, Environmental Health Program Supervisor.

Authority: Act No. 94-619, Alabama Legislature, Regular Session 1994.

History: Promulgated NOV. 9, 1994, Revised, November 8, 2000.

APPENDIX A

WARNING SIGN

DANGER - ULTRAVIOLET RADIATION

Follow instruction:

Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. Wear protective eyewear.

**FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT
IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.**

Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult a physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight.

If you do not tan in the sun, you are unlikely to tan from the use of this product.

APPENDIX B**MINIMUM DESIGN REQUIREMENTS FOR A TANNING DEVICE ROOM**

- A. **SPACE.** The length of the room shall not be less than the length of the tanning device plus one (1) foot. The width of the room shall not be less than the width of the bed plus two (2) feet. Each room shall not have less than 14 square feet of unobstructed floor space allotted to the consumer. This space shall be allotted excluding any encumbrance by the tanning device, such as overhangs and cables or similar encroachments. It may be any geometric configuration with no dimension of less than two (2) feet.
- B. **WALLS.** Room walls shall be at least seven (7) feet high and shall be permanently fixed to the floor or other structures as may be necessary.
- C. **DOOR OR MOVEABLE PANEL.** Door ways into the room shall be a minimum of 2.5 feet in width, shall be provided with a lock, and ventilation panels shall be provided for adequate ventilation of the interior of the room.
- D. **TIMING MECHANISM.** Each tanning device shall incorporate a timing mechanism which shall be under the control of the operator in a manner such that the consumer can not reset the timing mechanism without the knowledge of the operator. In addition, each tanning device shall incorporate a control on the device which enables the consumer being exposed to manually terminate radiation emission from the tanning device at any time without disconnecting the electrical plug or removing the ultraviolet lamp(s).
- E. **VENTILATION.** Each room shall be provided adequate ventilation to reduce the temperature below 100 degrees Fahrenheit.
- F. **DESIGN NOTE.** Each manufacturer produces tanning devices of various lengths. The design of a tanning room should reflect the possibility of utilization of larger tanning devices at a later date to avoid conflicts with the aforementioned design requirements.

APPENDIX C
REPORT OF INJURY FORM

Facility Information: _____

Facility Name:

|_____|

Address:

|_____|

City, State, Zip:

|_____|

Phone Number:

|_____|

Injury Information: _____

Name of injured party:

|_____|

Address:

|_____|

City, State, Zip:

|_____|

Phone Number:

|_____|

Date Injury Occurred:

|_____|

Description or Nature of Injury: _____

Name of Health Care Provider:

|_____|

Address:

|_____|

City, State, Zip:

| _____ |
Phone Number:
| _____ |

Physicians Report: _____

-

-

-

-

Injury Investigation: _____

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-

-

Sanitarian: _____

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GLOSSARY

Accessible Surface - means the external surface of the enclosure or housing provided by the manufacturer.

Act - means Act No. 582, Alabama Law, Regular Session, 1963. Codified as 22-14-1 Code of Alabama 1975.

Added Filtration - means any filtration which is in addition to the inherent filtration.

Agreement State - means any State with which the U.S. Nuclear Regulatory has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

Aluminum Equivalent - means the thickness of aluminum affording the same attenuation, under specified conditions, as the material in question.

Analytical X-ray Equipment - Means any device utilizing x-rays for the purpose of examining the microstructure of materials. This includes all types of x-ray defraction, fluorescence, and spectrographic analysis equipment.

Analytical X-ray System - means a group of local and remote components utilizing x-rays to determine 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, gonimeters, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices and control panels.

Assembler - means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem

Attenuation Block - means a block or stack, having dimensions seven (7) inches by seven (7) inches by 1.5 inches, of type 1100 aluminum alloy or other materials having equivalent attenuation.

Automatic Exposure Control - means a device which automatically controls one or more technique factors in order to obtain at a pre-selected location(s) a required quantity of radiation (see also **Phototimer**).

Barrier - (see **Protective Barrier**).

Beam Axis - means a line from the source through the center of the x-ray field.

Beam Monitoring System - means a system designed to detect and measure the radiation present in the useful beam.

Beam Limiting Device (BLD) - means a device which provides a means to restrict the dimensions of the x-ray field.

Cabinet Radiography - means industrial radiography conducted in an enclosure or interlocked cabinet shielded such that the x-ray producing machine will not operate unless the openings are closed and which cabinet is so shielded that radiation levels at every location on the exterior meet the limitations specified for an unrestricted area.

Calendar Quarter - means not less than twelve (12) consecutive weeks nor more than fourteen (14) consecutive weeks. The first calendar quarter in each year shall begin in January, and subsequent calendar quarters shall be so arranged 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 registrant shall change the method observed by him of determining calendar quarters for the purpose of these regulations except at the beginning of each calendar year.

Calibration - means the determination of the response or reading of an instrument relative to a series of known radiation values substantially over the range of the instrument or the strength of the source of radiation relative to a standard.

Cephalometric Device - means a device intended for the radiographic visualization and measurement of the dimensions of the head.

Certified Component - means the components of x-ray systems which are subject to the regulations promulgated under Public Law 90-602, "The Radiation Control for Health and Safety Act of 1968."

Certified X-ray System - means a x-ray system partially or wholly assembled from components manufactured since August 1, 1974, and bearing a label that the component complies with the Department of Health and Human Services performance standards 21 CFR, Sub-Chapter J.

CFR - means Code of Federal Regulations.

Changeable Filter - means any filter, exclusive of inherent filtration, which has been removed from the useful beam through any electronic, mechanical, or physical process.

Coefficient of Variation C - means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{S}{X} = \frac{1}{X} \left[\sum_{i=1}^n \frac{(X_i - X_{avg})^2}{(n-1)} \right]^{\frac{1}{2}}$$

where

n = Number of observations in sample.

S = Estimated std. deviation of the population.

X_{avg} = Mean value of observations in a sample.

X_i = ith observation in a sample.

Contact Therapy System - means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five (5) centimeters of the surface being treated.

Control Panel - means that part of the x-ray control on which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.

Cooling Curve - means the graphical relationship between the heat units stored and the cooling time.

Dead-man Switch - means a switch so constructed that the circuit closing contact can only be maintained by continuous pressure by the operator.

Department - means the Jefferson County Department of Health.

Detector - see **Radiation Detector**.

Diagnostic Source Assembly - means the tube housing assembly with the BLD attached.

Diagnostic-Type Tube Assembly - means a x-ray tube housing so constructed that with the port closed, the leakage radiation at a distance of one (1) meter in any direction from the target cannot exceed 100 milliroentgens in one (1) hour when a tube is operated at any of its specified

ratings.

Direct Scattered Radiation - means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam (see **Scattered Radiation**).

Dose - means absorbed dose or dose equivalent as appropriate.

- (a) **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**) (see SI equivalent **gray**).
- (b) **Dose Equivalent** - is a quantity that expresses in a common scale for all radiation a measure of postulated effect on a given organ. It is defined as the product of absorbed dose in rads and certain modifying factors. The special unit of dose equivalent is the rem (see **rem**). (see SI equivalent **sievert**.)

Entrance Exposure Rate - means the roentgens per unit time at the point where the center of the useful beam enters the patient.

Exposure - means the quotient of dQ/dm where dQ is the absolute value of the total charge of the ions of one sign produced in air where all 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 ,R.) (see SI equivalent **coulomb per kilogram**.)

For determining exposure to x-rays or gamma rays up to three (3) MeV, the dose limits in Part C, inclusive, may be assumed to be equivalent to the air dose. For the purpose of these rules, air dose means the dose measured by a properly calibrated appropriate in air at or near the body surface in the region of the highest dose rate.

Exposure Rate - means the exposure per unit time, such as roentgen per minute and milliroentgens per hour.

Fail Safe Characteristics - means a design feature which causes the beam port shutter to close, or otherwise prevents emergence of the primary beam upon failure of a safety or warning device.

Federal Performance Standards - Means the performance standards for ionizing radiation emitting products as defined in Part 1020, Subchapter J, Title 21 CFR.

Filter - means material placed in the useful beam to absorb, preferentially, the less penetrating radiation.

Fluoroscopic Imaging Assembly - means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) - such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and the diagnostic source assembly.

Full Beam Detector - means a radiation detector of such size that the total cross-section of the maximum size useful beam is intercepted.

General Purpose Radiographic X-ray System - means any radiographic system which, by design, is not limited to radiographic examinations of specific anatomical regions.

Gonadal Shield - means a protective barrier for the testes or ovaries.

Half-Value Layer - means the thickness of absorber required to reduce a beam of radiation to one-half (1/2) its incident exposure rate

Healing Arts - means the practice of dentistry, medicine, chiropractic, osteopathy, podiatry, and

for non-humans, veterinary medicine.

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 authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Health Officer - means the Health Officer of Jefferson County or his/her duly authorized representative.

Heat Unit - means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, (i.e., kVp x mA x t).

High Radiation Area - means any area, accessible to individuals, in which there exists radiation in such levels that a major portion of the body could receive in any one (1) hour a dose in excess of 100 millirems (1 millisievert).

Human Use - means the internal or external administration of radiation or radioactive materials to human beings.

Image Intensifier - means a device, installed in its housing, which instantaneously converts a x-ray pattern into a corresponding light image of high energy intensity.

Image Receptor - means any device, such as a fluoroscopic screen or radiographic film, which transforms incident x-ray photons into a visible image or into another form which can be made into a visible image by further transformation.

Image Receptor Support - means, for mammographic systems, that part of the system is designed to support the image receptor in a horizontal plane during mammographic examinations.

Individual - means any human being.

Inherent Filtration - means the filtration in the useful beam due to the window of the x-ray tube and any permanently tube enclosure.

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 Department.

Interlock - means a device arranged or connected such that the occurrence of an event or a condition is required before a second event or condition can occur or continue to occur.

Irradiation - means the exposure of matter to ionizing radiation.

JCRCR - means the Jefferson County Regulations for Control of Radiation.

Kilovolts Peak (kVp) - means the crest value in kilovolts of the potential of a pulsating potential generator.

Lead Equivalent - means the thickness of lead affording the same attenuation under specified conditions as the material in question.

Leakage Radiation - means all radiation, except the useful beam, coming from within the tube housing.

Leakage Technique Factors - means the technique factors associated with the tube housing assembly which are used to measure leakage radiation. They are defined as follows:

- (a) For capacitor storage energy equipment, the maximum rated peak tube potential and the maximum number of exposures in an hour for operation at the maximum rated kVp with the quantity of charge per exposure being ten (10) millicoulombs, i.e., ten (10) milliamperere seconds, or the minimum obtainable from the unit, whichever is larger.
- (b) For field emission equipment rated for pulsed operation, the maximum rated kVp and the maximum number of x-ray pulses in an hour for operation at the maximum rated kVp.
- (c) For all other equipment, the maximum rated kVp, and the maximum rated tube current for the maximum rated kVp.

Light Field - means the 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.

mA - means milliamperere.

mAs - means milliamperere second.

Mobile X-ray Equipment - means a unit that is not permanently fixed to a definite location in a building or vehicle.

Normal Operating Procedures - means 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.

Occupational Dose - means exposure of an individual to radiation in:

- (a) A restricted area; or
- (b) 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.

Open Beam Configuration - means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operations.

Person - means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Department, political subdivision of this State, or county, any other State or political subdivision or Department thereof, and any legal successor, representative, agent, or Department of the foregoing.

Personnel Monitoring Equipment - means devices such as film badges, pocket dosimeters, and TLD's designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual.

Phototimer - means a method for controlling radiation exposures to an image receptor by the amount of radiation which reaches a radiation monitoring device. The radiation monitoring device is part of the electronic circuit which controls the duration of time the tube is activated (see

Automatic Exposure Control Switch).

Physician - means an individual registered by the state to compound and distribute drugs in the practice of medicine or osteopathy.

Position Indicating Device (PID) - means a device on dental x-ray equipment used to indicate the beam position and used to establish a definite source-to-skin distance. It may or may not incorporate or serve as a BLD.

Positive Visual Warning Light - means a warning light which has redundant lights so that single failure will not prevent the warning light from functioning.

Possessing an X-ray Producing Machine - means using, operating, storing, manufacturing or otherwise having control of an x-ray producing machine in the County of Jefferson, State of Alabama.

Primary Beam - means ionizing radiation which passes through the aperture of the source housing by a direct path from the x-ray tube located in the radiation source housing.

Primary Protective Barrier - (see **Protective Barrier**).

Protective Apron - means an apron made of attenuating material and used to reduce radiation exposure.

Protective Barrier - means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

- (a) **Primary Protective Barrier** - means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.
- (b) **Secondary Protective Barrier** - means a barrier sufficient to attenuate the stray radiation to the required degree.

Protective Glove - means a glove made of attenuating materials used to reduce radiation exposure.

Qualified Expert - means an individual who has demonstrated to the satisfaction of the Department that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

rad - means the special unit of absorbed dose. One (1) rad equals one hundredth of a joule per kilogram (0.01 J/kg); for example, if tissue is the material of interest, then 1 (1) rad equals 100 ergs per gram of tissue (10 milligrays). (see SI equivalent **gray**.)

Radiation - the word "radiation" shall mean ionizing radiation, that is any electronic or particulate radiation capable of producing ions directly or indirectly in its passage through matter.

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:

- (a) One (1) hour a dose in excess of 5 millirems (0.05 millisievert), or
- (b) In any five (5) consecutive days a dose in excess of 100 millirems (1 millisievert).

Radiation Detector - means a device which in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation Machine - means any device capable of producing radiation except those which produce radiation only from radioactive material.

Radiation Producing Machine - means any device capable of producing radiation except those which produce radiation only from radioactive material.

Radiation Safety Officer - means one who has the knowledge and responsibility to apply appropriate radiation protection regulations.

Radiation Therapy Simulation System - means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

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.

Radiographer - means any individual who performs or personally supervises industrial radiographic operations and who is responsible to the registrant for assuring compliance with the requirements of these regulations and all license and/or certificate of registration conditions.

Radiographer's Assistant - means any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of his instruction.

Radiographic Imaging System - means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

Rating - means the operating limits as specified by the component manufacturer.

Recording - means producing a permanent form of an image resulting from x-ray photons (e.g., video tape).

Registrant - means any person who is registered with the Department pursuant to these regulations and the Act.

Registration - means registration with the Department in accordance with the regulations adopted by the Department.

rem - means a special unit of dose equivalent. For the purpose of these regulations, any of the following is considered to be equal to one rem:

- (a) An exposure of 1 roentgen of x or gamma radiation.
- (b) An absorbed dose of 1 rad due to x, gamma, or beta radiation.
- (c) An absorbed dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye.

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.

Restricted Area - means any area access to which is controlled by the registrant for purposes of protection of individuals from exposure to radiation and radioactive material. A 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.

Roentgen - means a unit of exposure to radiation. It is the amount of gamma or x-rays required to produce ions carrying one (1) electrostatic unit of electrical charge in one (1) cubic centimeter of dry air under standard conditions. (see **Exposure**).

Safety Devices - means a device such as a guard or interlock which prevents the entry of any portion of an individual's body into the primary beam path or which causes the beam to be shut off upon entry into its path.

Scattered Radiation - means secondary radiation or radiation that, during passage through matter, has been deviated in direction. (see **Direct Scattered Radiation**)

Secondary Protective Barrier - (see **Protective Barrier**).

Services - means the installing, calibrating, repairing, maintaining, or performing a radiation protection survey of an x-ray machine or associated x-ray component.

Shielded-room Radiography Using X-ray Producing Machines - means industrial radiography using x-ray producing machines which is conducted in an enclosed room, the interior of which is not occupied during the radiographic operation, which is also so shielded that every location on the exterior meets the conditions for an unrestricted area as specified in **Part C** and the only access to which is through openings which are interlocked so that the x-ray producing machine will not operate unless the openings are securely closed..

Shutter - means a device, generally of lead, fixed to an x-ray housing to intercept the useful beam.

Source - means the focal spot of the x-ray tube.

Source-image Receptor Distance (SID) - means the distance from the source to the center of the input surface of the image receptor.

Spot Check - means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.

Spot Film - means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film Device - means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

Stationary X-ray Equipment - (see **X-ray Equipment**).

Stray Radiation - means the sum of leakage and scattered radiation.

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 examinations, and measurements of levels of radiation or concentrations of radioactive material present.

Technique Factors - means the following conditions of operation:

- (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 diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Test - means the process of verifying compliance with an applicable regulation.

These Regulations - mean all Parts of the Jefferson County Department of Health's "Regulations to Govern the Production and Use of Radiation." revised (to be announced).

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.

Therapeutic Type Tube Housing - means an x-ray tube housing so constructed that the leakage radiation, with the port closed, at a distance of: (a) one (1) meter in any direction from the target cannot exceed one (1) roentgen in any one (1) hour; and (b) five (5) centimeters from any point accessible to the patient cannot exceed thirty (30) roentgens in any one (1) hour, when the tube is operated at any of its specified ratings.

Tube Rating Chart - means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

U.S. Department of Energy - means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

Unattended Operation - means any operation in which the analytical x-ray system is generating x-rays and an operator trained in accordance with Section H.6 of Part H is not physically present in the area sufficiently near the local components to prevent any operation which could cause an individual to exceed the limits given in **Part C**.

Unrestricted Area - means any area access to which is not controlled by the registrant for purposes of protection of individuals from exposure to radiation and radioactive material, and any area used for residential quarters.

Useful Beam - means that part of the radiation which passes through the window, aperture, cone, or other collimating devices of the tube housing.

Variable-Aperture BLD - means a BLD which has capacity for stepless adjustment of the x-ray field size at a given SID.

Visible Area - means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

Warning Light - means a red light above or near the entrance to a room that operates only when radiation is being produced or the capacity to produce radiation exists.

Wedge Filter - means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

Worker - means an individual engaged in work under a license or registration issued by the Department and controlled by a registrant, but does not include the registrant.

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 such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray Equipment - means an x-ray system, subsystem, or component thereof. 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) **Stationary X-ray Equipment** - means x-ray equipment which is installed in a fixed location.

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 (1/4) of the maximum in the intersection.

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.

X-ray Subsystem - means any combination of two (2) or more components of an x-ray system.

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 BLD, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray Tube - means any electron tube which is designed to be used primarily for the production of x rays.