



PUBLIC NOTICE OF PROPOSED RULE CHANGES

Pursuant to the Georgia Administrative Procedures Act, Official Code of Georgia (O.C.G.A.) § 50-13-1, et seq., the Georgia Department of Community Health is required to provide public notice of its intent to adopt, amend, or repeal certain rules other than interpretative rules or general statements of policy. Accordingly, the Department hereby provides notice of its intent to transfer and repeal the **Rules and Regulations for X-Ray, from Rules & Regs., R. 290-5-22 to new Chapter 111-8-90**. These changes are being proposed pursuant to the authority granted to the Department in O.C.G.A. §§ 33-21A-12 and 49-4-1. An exact copy of the revised rules and a synopsis of the revisions are attached to this public notice.

NOTICE OF PUBLIC HEARING

An opportunity for public comment will be held on September 15, 2020 at 11:30 a.m. via WebEx audio. There will be no in-person attendance at the Department of Community Health. The WebEx event number is **127 928 4924** and the event password is **"Public"**. Follow these instructions to join the event:

1. Copy the following link to a browser:
<https://dchevents.webex.com/dchevents/onstage/g.php?MTID=ea99b11bec64929b4f9731c1d5f56ffe0>
2. Click "Join Now".

Oral comments may be limited to ten (10) minutes per person. Individuals who are disabled and require assistance to participate during this meeting should contact the Office of General Counsel at (404) 657-7195 at least three (3) business days prior to the meeting.

Individuals wishing to comment in writing on any of the proposed changes should do so on or before September 18, 2020. Due to reduced physical staffing at the 2 Peachtree St. location in an attempt to limit the amount of exposure to COVID-19, DCH encourages written public comments submitted in accordance with O.C.G.A. 50-13-4(a)(2) to be submitted via e-mail to the following e-mail address: **PublicComment@dch.ga.gov**.



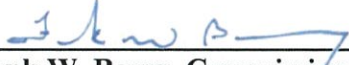
**GEORGIA DEPARTMENT
OF COMMUNITY HEALTH**

Any comments not able to be submitted via e-mail may be submitted via regular mail to the following address:

Attention: Mary Peterkin
Office of General Counsel
Georgia Department of Community Health
2 Peachtree Street, NW, 40th Floor
Atlanta, GA 30303

Comments from written and public testimony will be provided to the Board of Community Health prior to October 8, 2020. The Board will vote on the proposed changes on October 8, 2020.

NOTICE IS HEREBY GIVEN THIS 13th DAY OF AUGUST, 2020



Frank W. Berry, Commissioner

RULES OF
GEORGIA DEPARTMENT OF COMMUNITY HEALTH
HEALTHCARE FACILITY REGULATION DIVISION
REPEAL CHAPTER 290-5-22
AND
REPLACE WITH NEW CHAPTER 111-8-90
RULES AND REGULATIONS FOR X-RAY
SYNOPSIS OF REVISED RULES

STATEMENT OF PURPOSE:

The Department of Community Health proposes to repeal the Rules and Regulations for X-Ray under Chapter 290-5-22 and publish amended X-Ray Rules under Chapter number 111-8-90. This change is necessary to reflect that the X-Rays are subject to regulation by the Department of Community Health rather than the Department of Human Resources, which has since been renamed as the Department of Human Services. These rules are being proposed pursuant to the authority granted to the Department of Community Health in O.C.G.A. §§ 31-2-4, 31-2-5, and 31-13-5.

MAIN FEATURES OF THE PROPOSED RULE:

The proposed Rules and Regulations for X-Ray, Chapter 111-8-90, update the existing rules by replacing the Chapter number, replacing the name of the Department, and correcting rule numbering and grammatical errors. The proposed Rules and Regulations for X-Ray, Chapter 111-8-90, do not change any substantive provisions of the existing rule.

RULES OF
GEORGIA DEPARTMENT OF ~~HUMAN SERVICES~~ COMMUNITY HEALTH
DIVISION OF ~~PUBLIC HEALTH~~ HEALTHCARE FACILITY REGULATION

CHAPTER ~~290-5-22~~ 111-8-90

RULES AND REGULATIONS FOR HOSPITAL CARE FOR X-RAY

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Rule ~~290-5-22~~ 111-8-90-.01 General Provisions

- (1) Purpose and Scope.
 - (a) To set forth rules and regulations which implement the mandates of the Radiation Control Act, O.C.G.A. Chapter 31-13, as it relates to the registration and regulation of users of radiation machines.
 - (b) Except as otherwise specifically provided, these regulations apply to all uses of radiation machines in the healing arts, industry, educational and research institutions.
- (2) Human Radiation Exposure. Radiation shall not be applied to individuals except as prescribed by persons licensed to practice in the healing arts or as otherwise provided in these regulations. Only licensed practitioners and authorized operators shall apply radiation to a person.
- (3) Prohibited Use. The operation of any radiation machine in this state is prohibited unless the user is registered with the Department.

- (4) Definitions. Unless a different meaning is required by the context of a rule, the terms used in these regulations have the definitions set forth below.
- (a) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
 - (b) "Act" means the Radiation Control Act, Chapter 13 of Title 31 of the Official Code of Georgia Annotated.
 - (c) "Analytical x-ray machine" means any device, including but not limited to x-ray diffraction, x-ray diffractometry, and x-ray spectroscopy, which utilizes x-rays to examine the micro-structure of materials.
 - (d) "Aperture" means any opening in the external surface, other than a port, which remains open during the production of x-rays.
 - (e) "Applicant" means the responsible person in authority who applies for registration of the x-ray machine(s).
 - (f) "Barrier" means attenuating materials used to reduce radiation exposure:
 - 1. "Primary-barrier" is one sufficient to attenuate the useful beam to the required degree as specified in section ~~290-5-22~~ 111-8-90-.03 of this chapter.
 - 2. "Secondary-barrier" is one sufficient to attenuate the sum of leakage and scattered radiation to the required degree as specified in section ~~290-5-22~~ 111-8-90-.03 of this chapter.
 - (g) "Beam-limiting device" or "collimating device" means a device which provides a means to restrict the dimensions of the x-ray field.
 - (h) "Beam scattering filter" means a filter used in order to scatter a beam of electrons.
 - (i) "Cabinet x-ray machine" means an x-ray machine with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray machine is intended to:

1. contain at least that portion of a material being irradiated;
2. provide radiation attenuation; and
3. exclude personnel from its interior during generation of radiation.

Included are all x-ray machines designed primarily for the inspection of carry on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray machine.

- (j) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter.
- (k) "Certified machine" means any x-ray machine which has one or more certified component(s) as specified in the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, Part 1020.30.
- (l) "Contact therapy machine" means an x-ray machine used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.
- (m) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.
- (n) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure.
- (o) "Department" means the Department of ~~Human Resources~~ Community Health.
- (p) "Diagnostic type tube housing" means an x-ray tube housing so constructed that the leakage radiation at a distance of 1

meter from the target cannot exceed 100 mR in 1 hour when the tube is operated at any of its specified ratings.

- (q) "Diagnostic x-ray machine" means an x-ray machine designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.
- (r) "Disposal" for the purpose of these regulations, means the sale, gift, transfer, destruction, disassembly or any disposition of a radiation machine or its parts.
- (s) "Dose" as used in these regulations shall mean absorbed dose or dose equivalent as appropriate.
 - 1. "Absorbed Dose" means energy absorbed per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the Rad (see "Rad") or Gray (see "Gray").
 - 2. "Dose equivalent" is a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. The unit of dose equivalent is the rem (see "Rem") or Sievert (see "Sievert").
- (t) "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.
- (u) "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.
- (v) "Existing equipment" means therapy machines subject to these regulations which were manufactured on or before January 1, 1985.
- (w) "Exposure" means a measure of the ionization produced in a given volume of air by X- or gamma radiation. The unit of exposure is the Roentgen or coulombs/kilogram.
- (x) "Exposure rate" means the exposure per unit of time, i.e., as Roentgens per minute, or mR per hour as measured in air. (coulombs/kilogram/unit time).

- (y) "External surface" means the outside surface of the cabinet x-ray machine including the plane across any aperture or port.
- (z) "Facility" means the location at which one or more x-ray machines are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.
- (aa) "Failsafe" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.
- (bb) "Filtration" means material in the useful beam which preferentially absorbs selected radiations.
 - 1. "Added filtration" means any filtration which is in addition to the inherent filtration.
 - 2. "Inherent filtration" means the filtration of the useful beam provided by the permanently installed tube assembly.
 - 3. "Total Filtration" means the sum of the added filtration and inherent filtration in the useful beam.
- (cc) "General purpose radiographic x-ray machine" means any radiographic x-ray machine which, by design, is not limited to radiographic examination of specific anatomical regions.
- (dd) "Gray" (Gy) means unit of absorbed dose. One Gy equals 1 Joule of energy deposited in one kilogram of material. One gray equals one hundred rads.
- (ee) "Half-value layer" means the thickness of specified material which attenuates the beam of radiation so that the exposure is reduced to one-half of its original value.
- (ff) "Healing Arts" means the practice of medicine, chiropractic, dentistry, osteopathy, podiatry, and veterinary.
- (gg) "High Radiation Area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirems.

- (hh) "Human use" means the administration of radiation to an individual.
- (ii) "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images.
- (jj) "Inspection" means an official examination or observation to be performed by the Department including but not limited to, tests, surveys, evaluations and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the Department.
- (kk) "Irradiation" means the exposure of matter to ionizing radiation.
- (ll) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- (mm) "Leakage radiation" means radiation emanating through the diagnostic or therapeutic source assembly except for the useful beam.
- (nn) "Leakage technique factors" means the technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:
 - 1. For capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 millampere seconds, or the minimum obtainable from the unit, whichever is larger.
 - 2. For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
 - 3. For all other equipment, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

- (oo) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor.
- (pp) "New equipment" means x-ray machines subject to these regulations which were manufactured after January 1, 1985.
- (qq) "Occupational dose" means exposure of an individual to radiation in the course of employment in which the individual's routine duties involve exposure to radiation.
- (rr) "Open beam x-ray installation" means an installation in which the source and all objects exposed to the radiation source are within an area designated as a high radiation area.
- (ss) "Operator" means that individual authorized by the registrant to operate the registrant's x-ray machine(s).
- (tt) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.
- (uu) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing.
- (vv) "Personnel monitoring equipment" means devices (i.e., film badges, pocket dosimeters, and thermo-luminescent dosimeters) designed to be worn or carried by an individual for the purpose of estimating the dose received.
- (ww) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.
- (xx) "Port" means any opening in the external surface which is designed to remain open during the production of x-rays for the purpose of conveying material to be irradiated into or out of the machine or for partial insertion for irradiation of material whose dimensions do not permit the insertion of the entire object into the cabinet.

- (yy) "Practitioner" means a physician licensed in Georgia under authority of Chapter 34 of Title 43 of the Official Code of Georgia Annotated; a chiropractor licensed in Georgia under authority of Chapter 9 of Title 43 of the Official Code of Georgia Annotated; a podiatrist licensed in Georgia under authority of Chapter 35 of Title 43 of the Official Code of Georgia Annotated; a dentist licensed in Georgia under authority of Chapter 11 of Title 43 of the Official Code of Georgia Annotated; or a veterinarian licensed in Georgia under authority of Chapter 50 of Title 43 of the Official Code of Georgia Annotated.
- (zz) "Precertified x-ray systems" means a diagnostic x-ray machine produced prior to August 1, 1974 as specified in the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, Part 1020.30.
- (aaa) "Rad" (radiation absorbed dose) means the unit of absorbed dose. One rad = 100 ergs/gm or .01 Gy.
- (bbb) "Radiation" means gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles.
- (ccc) "Radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 millirems, or in any 5 consecutive days a dose in excess of 100 millirems.
- (ddd) "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.
- (eee) "Radiation Machine" means any device that is designed for the controlled production of radiation or nuclear particles.
- (fff) "Radiation Therapist" shall be defined as a physician who has met the requirements for certification by the American Board of Radiology in radiation therapy or by the American Board in general radiology provided that the physician has had two years or more of additional experience in radiation therapy.

(ggg) "Radiation therapy simulation machine" means a radiographic or fluoroscopic x-ray machine specifically designed for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

(hhh) "Registrant" means any user registered with the Department in accordance with these regulations.

(iii) "Registration" means registration of the user(s) of x-ray machine(s) with the Department.

(jjj) "Regulations" means the Department of ~~Human Resources~~ Community Health Rules and Regulations for X-Ray, Chapter ~~290-5-22~~ 111-8-90.

(kkk) "Rem" means a measure of the dose equivalent of any radiation to body tissue in terms of its estimated biological effect relative to a dose received from an exposure to one roentgen (R) of x-rays. For the purpose of these regulations, any of the following is considered to be equivalent to a dose of one rem:

1. An exposure of 1 R of x-, or gamma radiation.
2. A dose of 1 rad (.01 Gy) due to x-, gamma, or beta radiation.
3. A dose of 0.05 rad (5×10^{-4} Gy) due to particles heavier than protons and with sufficient energy to reach the lens of the eye.
4. A dose of 0.1 rad (1×10^{-3} Gy) due to neutrons or high energy protons.

(III) "Restricted area" (controlled area) means any area to which access is controlled by the registrant for purposes of protection of individuals from exposure to radiation. "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.

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

- (nnn) "Sale" for the purpose of these regulations, means any act where a radiation machine is transferred from one person to another for money or other valuable consideration.
- (ooo) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.
- (ppp) "Shielded-room radiography" means industrial radiography conducted in a room so shielded that radiation levels at every location on the exterior meet the limitations specified in Section .03 of these regulations.
- (qqq) "Sievert" (Sv) means a unit of dose equivalent. One sievert equals 100 rem.
- (rrr) "Source" means the focal spot (target) of the x-ray tube.
- (sss) "Source-image receptor distance" (SID) means the distance from the source to the center of the input surface of the image receptor.
- (ttt) "Spot check" means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.
- (uuu) "Target" means that part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.
- (vvv) "Test" means an examination through the use of instrumentation, visual inspection, interviews with individuals, and checks of various devices used in connection with radiation generating equipment to determine compliance with a regulatory requirement.
- (www) "Therapy radiation" means the use of an ionizing radiation source for the purpose of treatment.
- (xxx) "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.
- (yyy) "Transfer" for the purpose of these regulations, means the disposing of a radiation machine by any means including, but not limited to gift, sale, bailment, loan or lease.

(zzz) "Unrestricted area" (uncontrolled area) means any area to which access is not directly controlled by the registrant for purposes of protection of individuals from exposure to radiation.

(aaaa) "Unwanted by-product" means ionizing radiation generated by an apparatus whose primary function and design is not intended to produce ionizing radiation.

(bbbb) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

(cccc) "User" means any person who possesses a radiation machine which is utilized for the administration of radiation.

(dddd) "Virtual source" means a point from which radiation appears to originate.

(eeee) "X-Ray machine " for the purposes of these regulations means a radiation machine designed for the controlled production of x-rays.

(5) Variances, Waivers, and Exemptions. The Department may, upon application, grant such variances, waivers, or exemptions from the requirements of these regulations as authorized by O.C.G.A. Section 31-2-4.

(6) Inspections.

(a) The Department is the authorized agency empowered to inspect and determine compliance with the Act and these regulations.

(b) Each registrant shall afford the Department at all reasonable times opportunity to inspect radiation machines and the premises and facilities wherein such radiation machines are used.

(c) Each registrant shall make available to the Department for inspection, upon reasonable notice, records maintained by the registrant pursuant to this Chapter.

- (d) The Department shall conduct periodic inspections of registrants to determine compliance with the Act and this Chapter.
- (e) The Department or its designated representative is authorized under the authority of O.C.G.A. Section 31-5-5(b) to classify as confidential and privileged documents, reports and other information and data obtained by them from persons, firms, corporations, municipalities, counties, and other public authorities and political sub-divisions where such matters relate to:
 - 1. Trade secrets and commercial or financial information furnished to the Department on a privileged or confidential basis. Matters subject to this exemption are those which are customarily held in confidence by the originator. They include, but are not limited to:
 - (i) Information received in confidence, such as trade secrets, inventions, and proprietary data;
 - (ii) Technical reports and data, designs, drawings, specifications, formulas, or other types of proprietary information which are furnished to the Department or which are generated or developed by the Department or for the Department under contract.
 - 2. Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Examples of files exempt from disclosure include, but are not limited to:
 - (i) Names or identifying information regarding individuals.

Discovery shall be subject to the statutory requirements found in O.C.G.A. Section 31-5-5.
- (f) Whenever the Department finds that an emergency exists requiring immediate action to protect the public health and safety, the Department may, without notice or hearing, issue an order reciting the existence of such emergency and requiring that such action be taken as is necessary to meet the emergency. Notwithstanding any provision of Chapter 13 of

Title 31 of the Official Code of Georgia Annotated, such order shall be effective immediately. Any person to whom such order is directed shall comply therewith immediately but on application to the department shall be afforded a hearing within ten days. On the basis of such hearing the emergency order shall be continued, modified or revoked within 30 days after such hearing, as the Department may deem appropriate under the evidence.

(7) Tests.

(a) The Department has the authority to conduct such reasonable tests as it deems appropriate or necessary in the administration of this Chapter, including, but not limited to, tests of:

1. sources of radiation;
2. facilities wherein sources of radiation are used or stored;
3. radiation detection and monitoring instruments; and
4. other equipment and devices used in connection with utilization or storage of registered sources of radiation.

(8) Requirements for Radiation Protective Shielding.

(a) Each facility shall be provided with such primary barriers and/or secondary barriers as necessary to assure compliance with Section .03(2)(a) and (b) of these Regulations titled "Standards for Protection Against Radiation".

(b) In computing shielding requirements, only identified permanently installed construction materials or permanently installed lead shielding materials shall be considered. Cassettes, cassette holders, (except as specifically permitted elsewhere in this Chapter), patients, or non-permanent materials shall not be used as part of the radiation shielding.

1. For energies up to 1 MeV:
 - (i) This requirement shall be deemed to be met if the thickness of the barrier(s) is equivalent to that computed in accordance with National Council on Radiation Protection and Measurements (NCRP) Report No.49 "Structural Shielding Design and

Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" or its current revision or replacement.

- (ii) A primary barrier in walls shall extend from the floor to a minimum height of 84 inches and shall have a width broad enough to intercept the entire cross section of the useful beam plus an extension of at least one foot (30 cm) on each side of the barrier at the maximum SID used with the maximum beam dimensions permitted by the beam limiting device. All sections of the wall or adjacent areas including the floor that may be struck by the useful beam shall be considered primary barriers.
 - (iii) In calculating radiation shielding requirements workloads shall be realistic, but in no case, except for intra-oral dental x-ray facilities, less than 15 milliamperere minutes (mAm) per week at 100 kVp, or at the maximum stated energy of the x-ray machine if it is less than 100 kVp.
2. For energies of 1 MeV or greater: This requirement shall be deemed to be met if the thickness of barrier(s) is equivalent to that computed in accordance with the National Council on Radiation Protection and Measurements (NCRP) Report No.51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities," or its current revision or replacement.
- (c) Non-healing arts facilities shall meet the shielding design criteria described in .01(8)(a) and (b).
 - (d) During the construction phase, the installation of shielding shall be evaluated pursuant to procedures outlined in NCRP Handbook 49 or NCRP Handbook 51 or its current revision or replacement. The registrant is responsible for ensuring that such evaluation is performed by an individual competent to perform such evaluation.
 - (e) Facilities may be required to have a radiation integrity survey of the completed installation to assure that:

1. materials used for shielding are not impaired by joints, openings for duct pipes, conduits, etc., passing through or embedded in the wall; and
2. such materials meet the minimum lead equivalency as stated in submitted design.

The registrant is responsible for ensuring that such survey is performed by an individual competent to perform such survey.

- (f) The final assessment of the adequacy of the design and construction of structural shielding shall be based on a radiation survey of the completed installation. If the radiation survey shows deficiencies, additional shielding and/or modifications shall be provided to the satisfaction of the Department.

(9) Shielding Design Plan Review.

- (a) Shielding designs, to include facility layout and machine orientation, shall be submitted to the Department for approval prior to the construction of a new facility or the modification (i.e., reorientation of equipment, increased workload, exchange of radiation machine, etc.) of an existing facility using radiation machines for:

1. Diagnostic or therapeutic purposes in the healing arts.
2. Non-healing arts applications which includes, but is not limited to, industrial applications.

- (b) Radiation shielding designs submitted for review shall contain at least the following information.

1. The location of the radiation machine; Name, Address, Room number; and
2. Travel and traverse limits permitted by the manufacturer; direction(s) of the useful beam; locations of windows and doors; the location of the operator's booth; and the location and dimensions of the x-ray control panel; and
3. The structural composition and thickness or lead equivalency of all walls, doors, partitions, floors, and

ceiling of the room(s) when considered as part of the shielding requirements; and

4. The dimensions of the x-ray room(s); and
5. The occupancy of all adjacent areas inclusive of space above and below the x-ray room(s); and
6. The maximum technique factors which are anticipated; and
7. The type and number of examination(s) or treatment(s) which will be performed with the equipment, or
8. The anticipated workload of the radiation machine(s) in milliamp minutes per week (or rads/week at 1 meter for therapy machines only) at the maximum anticipated operating energy.

(c) X-Ray Room Design Requirements:

1. Healing Arts:
 - (i) Except for dental, dedicated podiatric and veterinary x-ray facilities, in all x-ray facilities built or modified after the effective date of these regulations, the x-ray room shall have minimum dimensions of 8 feet (2.4 m) by 10 feet (3.0 m) sufficient to assure source-to-image distances equal to those currently accepted in the healing arts to make standard radiographs of anatomical regions.
 - (ii) There shall be sufficient work space allotted to the x-ray assistants to set up procedures.
2. Other than healing arts. Sufficient space shall be allotted to adequately perform duties and assure radiation safety.

(d) Radiation Machine Operator's Protective Barrier.

1. Diagnostic x-ray facilities other than dental intraoral, dental panoramic, and veterinary, built or modified after the effective date of these regulations shall have a fixed operator's barrier.
 - (i) Design Requirements for fixed operator's barrier.

- (I) The operator shall be allotted not less than 7.5 square feet (.697 sq.m.) of unobstructed floor space in the booth.
- (II) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).
- (III) Structural Requirements:
 - I. The barrier walls shall be permanently fixed and have a height of at least 7 feet (2.13 m) from the floor.
 - II. When a door or movable panel is used as an integral part of the structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.
 - III. The barrier shall intercept any radiation that has been scattered only once and will ensure that the limit of 100 mrem/wk (1 mSv/week) permitted for personnel exposure shall not be exceeded. Design guidelines should consider 10 mrem/week (.1 mSv/week).
- (ii) Radiation Machine Control Placement:
 - (I) The x-ray control for the machine shall be fixed within the booth and:
 - (II) placed so that the operator cannot conveniently leave the protection of the barrier during an exposure, and
 - (III) will permit the operator to conveniently use available viewing devices.
- (iii) Viewing Device Requirements for Medical Facilities:
 - (I) Each booth or barrier shall be equipped with at least one viewing device which will be so placed

that the operator can easily view the patient during any exposure.

(II) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements.

(III) When the viewing system is by electronic means:

I. the camera shall be so located as to accomplish the general requirements, and

II. there shall be an equivalent viewing system as a backup for the primary system.

2. Portable barriers may be substituted for .01(9)(d)1. where fixed barriers are inappropriate for the x-ray procedures but only upon written application to the Department stating the reasons a portable operator's barrier is necessary.

3. Design Requirements for Portable barriers.

(i) The barrier shall meet shielding and viewing requirements of .01(9)(d)1. (i) and (iii).

(ii) Clear instructions on the placement and use of the barrier shall be posted on the operator's side of the barrier.

4. Lead aprons shall be used by persons who assist in procedures where holding or close contact with a patient undergoing an x-ray procedure is required.

(10) Copy of Design Maintained. A copy of the shielding design as submitted to and approved by the Department shall be kept on file at the facility.

(11) Compliance. After receiving written notice that specific areas of non-compliance with these rules and regulations exist in a registered x-ray facility, the registrant shall make required corrections and notify the Department of the action(s) taken within the time authorized by the Department which shall not exceed 60 days.

(12) Impounding.

- (a) In the event of an emergency, the department shall have the authority to 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 the provisions of the Act or these regulations.
- (b) The department may release such sources of radiation to the owner thereof upon terms and conditions in accordance with the Act and these regulations or may bring an action in the appropriate superior court for an order condemning such sources of radiation and providing for their destruction or other disposition so as to protect the public health and safety.

(13) Rules and Regulations. Each registrant shall possess a current copy of the Rules and Regulations for X-Ray, Chapter ~~290-5-22~~ 111-8-90, which shall be maintained in the registered facility.

Authority: Ga. L. 1964, pp. 507, 569, 570; O.C.G.A. Secs. 31-13-3, 31-13-5, 31-13-8

Rule ~~290-5-22~~ 111-8-90-.02 Registration

(1) Registration.

- (a) All users of radiation machines in Georgia are required to register with the Department.
- (b) Application for registration shall be on forms provided by the Department.
- (c) The user shall complete a separate application for registration for each facility at which he possesses a radiation machine.
- (d) The user applying for initial registration shall certify to the Department in his registration application that he has determined through inspection that he is in compliance with these regulations. The user shall also certify that, when registered, he will use his machines in compliance with all standards set by the Department. For purposes of registration, inspections may be performed by employees of the Department. Should the user elect to obtain the services of persons other than employees of the Department, for the purpose of performing an inspection for certifying to the Department that his facility and machines are in compliance

with these regulations prior to initial registration, the user shall insure that the individual possesses one set of the qualifications listed in .02(4):

(e) Additional requirements for initial registration.

1. The user shall submit shielding specifications for each facility for which he is registering.
2. The user is responsible to document that the required shielding was installed in accordance with design specifications. A report certifying test results shall be sent to the Department and a copy maintained at the facility.

(i) Tests shall be made pursuant to the procedures outlined in the National Council on Radiation Protection: Report 35 Dental X-Ray Protection; Report 49 Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 Mev; Report 51 Radiation Protection Guidelines for 0.1-100 Mev Particle Accelerator Facilities; or, the published guidelines of other recognized authorities in the field of radiation protection.

3. Cabinet x-ray systems in addition to .02(1) of this rule, persons applying for registration shall provide written verification to the Department that the cabinet x-ray system is installed and operating in accordance with the manufacturer's design specifications.

(f) The user of any radiation machine shall not initially place such machine in operation prior to registration with the Department.

(g) Registration of Out of State Machines.

1. When any radiation machine is to be brought into the state of Georgia and operated, the person proposing to bring such machine into the state of Georgia shall give written notice to the Department at least five (5) working days before such machine enters the state. The notice shall include the type of radiation machine the nature, duration, and scope of use; and the exact location(s) of use. Telephone notification may be used in cases where the five day notice would pose an undue hardship, but

such notification shall be confirmed in writing as soon as possible thereafter.

2. In addition, the out-of-state person shall comply with all applicable requirements of these regulations and supply the Department with such other information as the Department may reasonably request.
- (2) Registration of Particle Accelerators. In addition to (1) of this rule persons applying for registration of particle accelerators shall submit the supplemental information required in Rule ~~290-5-22 111-8-90~~.05(3) and if the particle accelerator is for human use the information required in Rule ~~290-5-22 111-8-90~~.05(4).
- (3) Failure to register as provided in .02(1) shall subject the offending person to a civil penalty not to exceed \$1000.00, and any other legal remedies available as required in O.C.G.A. 31-13-15.
- (4) Formal Education or Certification plus Experience.
 - (a) Bachelor's degree in a physical science or mathematics.

Four years of applied health physics experience in a pro-gram with radiation safety problems similar to those in the program to be surveyed.
 - (b) Bachelor's degree in a physical science or a biological science with a physical science minor, and one year of graduate work in health physics.

Three years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed.
 - (c) Master's degree in health physics or radiological health.

Two years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed.
 - (d) Doctor's degree in health physics or radiological health.

One year of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed.

- (e) Certification by the American Board of Health physics or by the American Board of Radiology, or be a Fellow, Canadian College of Physicists in Medicine.

One year of applied health physics experience in a program with radiation safety problems similar to those in a program to be surveyed.

- (5) The user shall maintain on file the qualifications of the non-Departmental individuals performing the inspection for purposes of initial registration.
- (6) Renewal of Registration. Every registrant possessing a radiation machine shall renew registration at intervals as required by the Department.
- (7) Report of Changes. The registrant shall notify the Department writing of any changes which would render the information contained in the current registration inaccurate. Notification of any changes in the radiation machine's location, shielding, operation, safety features, or occupancy of adjacent areas must also be made to the Department, and may require a radiation safety survey and re-registration prior to continued operation of the machine.
- (8) Report of Sale, Lease, Transfer, or Disposal. Any person who sells, leases, transfers, or otherwise disposes of a radiation machine shall notify the Department in writing. Written notification shall include, when applicable, the name and address of the new owner or lessee, and/or facility, the date of the transaction, and the model and serial number of the machine or machines.
- (9) Exemptions:
 - (a) Electronic equipment that produces radiation incidental to its operation for other purposes (i.e. television receivers) is exempt from the registration and notification requirements of this part, provided the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mRem per hour at 5 cm. from any accessible surface of such equipment. Production, testing, or factory service of such equipment shall not be exempt.
 - (b) Radiation machines while inoperable or in transit or storage are exempt from the requirements of these regulations.

- (10) Revocation. Registration may be revoked by the Department for failure to comply with or maintain compliance with Chapter 13 of Title 31 of the Official Code of Georgia Annotated or the provisions of this Chapter. Prior to revocation of any registration, the registrant shall be given notice of the grounds for revocation and shall have an opportunity to show cause why the revocation action should not proceed as provided in Article 1 of Chapter 5 of Title 31 of the Official Code of Georgia Annotated.

Authority: Ga. L. 1964, pp. 507, 569, 570; O.C.G.A. Secs. 31-13-5, 31-13-8, 31-13-10.

Rule ~~290-5-22~~ 111-8-90-.03 Standards for Protection against Radiation

(1) General Provisions.

- (a) If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron absorbed dose in rads (grays), one rem (.01 Sv) of neutron radiation may, for purposes of these regulations, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

Neutron Flux Dose Equivalents

Neutron energy (MeV)	Number of neutrons per square centimeter for a dose equivalent of 1 rem (neutrons/cm ²)	Average flux density to deliver 100 millirems (1 millisievert) in 40 hours (neutrons/cm ² per second)
Thermal	0.1	5.0
0.00001	0.5	7.5
0.005	1.0	10.0
0.02	2.5	10 to 30

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9.7×10^6	2.6×10^5	80
7.2×10^6	2.4×10^5	30
8.2×10^6	2.4×10^5	18
4.0×10^6		20
1.2×10^6	1.4×10^5	18
4.3×10^5	670	
	500	17
2.6×10^5		17
	570	
2.9×10^5	280	10

(b) For determining the doses specified in this section, a dose from x or gamma radiation up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air, at or near the body surface in the region of highest exposure rate.

(c) Dose to the whole body shall include any dose to the entire body or any major portion thereof, gonads, active blood-forming organs, head and trunk, or lens of the eye.

(2) Permissible Doses.

(a) Occupational Exposure

1. Except as provided in .03(2)(a)2., no registrant shall possess, own, use, or receive, sources of radiation in such a manner as to cause an occupationally exposed individual to receive, from all sources of radiation in the possession of the registrant, a dose in excess of the limits in the following table:

	Rems (Sv) Per Calendar Quarter
Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads.....	1 ¼ rem (12.5 mSv)
Hands and forearms; feet and ankles.....	18-3/4 rem (187.5 mSv)
Skin of whole body.....	7 ½ rem (75 mSv)

2. A registrant may permit an occupationally exposed individual to receive a dose to the whole body greater than that permitted under .03(2) (a) 1. provided:
 - (i) during any calendar quarter the dose to the whole body from sources of radiation in the possession of the registrant shall not exceed 3 rem (30 mSv);
 - (ii) the dose to the whole body when added to the accumulated occupational dose to the whole body shall not exceed 5 (N-18) rem [50(N-18)mSv], where "N" equals the individual's age in years at his last birthday; and
 - (iii) the registrant has determined the individual's accumulated occupational dose to the whole body on a Department form, or on a clear and legible record containing all the information required on that form.
3. Individuals under 18 years of age in x-ray training schools or employed in occupations which involve exposure to ionizing radiation shall have a personnel radiation monitoring device and shall not be permitted to receive a dose to the whole body in excess of 10% of the dose permitted in .03(2)(a)1.

(b) Non-Occupational Exposure.

1. The dose limits for individuals employed in occupations which do not normally involve exposure to ionizing

radiation shall be one-tenth of the occupational limits under .03(2)(a)1., excluding medical radiation for the purpose of diagnosis or therapy.

2. For the purposes of these regulations the embryo/fetus shall be considered to be a separate entity distinct from the occupationally exposed woman carrying it, and shall not be subject to occupational limits.
3. The embryo/fetus shall not be exposed to doses in excess of 50 mrem in any one month after the pregnancy is known. The total dose equivalent limit to the embryo/fetus shall not exceed 500 mrem over the period of gestation.

(c) Radiation Levels in Unrestricted (Uncontrolled) Areas.

1. Except as authorized by the Department pursuant to .03(2)(c)2., no registrant shall possess, own, or use sources of radiation in such a manner as to create in any uncontrolled area from such sources of radiation in his possession radiation levels which, if an individual were continuously present in the area, could result in an individual receiving:
 - (i) a dose in excess of two millirems in any one hour; or
 - (ii) a dose in excess of 100 millirems in any seven consecutive days.
2. Any registrant or prospective registrant may apply to the Department for proposed limits upon levels of radiation in uncontrolled areas in excess of those specified in .03(2)(c)1., resulting from the applicant's possession or use of sources of radiation. Such applications should include information as to anticipated average radiation levels and anticipated occupancy times for each uncontrolled area involved. The Department may approve the proposed limits if the applicant demonstrates to the satisfaction of the Department that the proposed limits would not cause an individual to receive doses to the whole body in any period of one calendar year in excess of 0.5 rem (5.0 mSv).

(3) Personnel Monitoring.

- (a) Except as provided in .03(3)(c), each registrant shall supply appropriate personnel radiation monitoring devices and shall require the use of such equipment by:
 - 1. Each individual who enters a controlled area under such circumstances that the individual receives, or is likely to receive, a radiation dose in any calendar quarter in excess of 25 percent of the applicable values specified in .03(2)(a)1. for occupational exposure;
 - 2. Each individual under 18 years of age who enters a controlled area under such circumstances that the individual may receive a radiation dose in excess of 10 percent of the applicable value specified in .03(2)(a)1.
 - 3. Each individual who enters a high radiation area.
 - (b) All individuals required to use personnel monitoring equipment shall be instructed in its proper use and purpose.
 - (c) Personnel monitoring will not be required for individuals undergoing diagnostic or therapeutic procedures.
 - (d) When using protective aprons, personnel monitoring shall be worn outside the apron at collar level.
- (4) Caution Signs, Labels, and Signals.
- (a) Radiation Symbol
 - 1. Except as otherwise authorized by the Department, the symbol prescribed by this section is the conventional three-bladed warning sign commonly used in the radiological professions and shall use the conventional radiation caution colors (magenta or purple on yellow background).
 - 2. In addition to the contents of signs and labels prescribed in these regulations, a registrant may provide any additional information on or near such signs and labels to indicate the nature of the radiation source, type of radiation, limits of occupancy, and similar precautionary information which may be appropriate in aiding individuals to minimize exposure to radiation.

- (b) Radiation Areas. Each radiation area, except areas where diagnostic and therapeutic radiation machines are used solely in the healing arts, shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words: CAUTION - RADIATION AREA.
- (c) High Radiation Areas. Each high radiation area, except areas where diagnostic and therapeutic radiation machines are used solely in the healing arts, shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words: CAUTION - HIGH RADIATION AREA.
- (d) Radiation Generator Warning Signals. Each radiation generator, except radiographic and fluoroscopic radiation machines used solely in the healing arts, which is capable of producing, in any area accessible to individuals, a dose rate in excess of 100 millirems per hour, shall be provided with a warning signal or light at the generator. Such a signal or light shall be so connected as to be activated automatically when the exposure switch is "on" in order to provide adequate warning against entering the area.

Authority: Ga. L. 1964, pp. 507, 569, 570; O.C.G.A. Sec. 31-13-5.

Rule ~~290-5-22~~ 111-8-90-.04 X-Rays in the Healing Arts

- (1) Scope. This part establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized in accordance with State statutes to engage in the healing arts. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.
- (2) General Requirements.
 - (a) Training of Operators who Administer X-ray in the Healing Arts.
 - 1. The registrant shall assure the Department that all radiation machines and associated equipment under his control are operated only by individuals instructed in safe operating procedures.
 - 2. The registrant shall require persons operating his radiation machine and associated equipment to receive,

at a minimum, six hours of instruction. The following subject categories shall be covered:

- (i) Protection Against Radiation
 - (I) Protective Clothing
 - (II) Patient Holding
 - (III) Time, Distance, Shielding
 - (IV) Radiation Protection Standards
 - (ii) Dark Room Techniques
 - (I) Developing Chemicals
 - (II) Film Protection
 - (III) Cassettes
 - (IV) Screens
 - (iii) Patient Protection
 - (I) Beam Limitation
 - (II) Setting Up Techniques
 - (III) Biological Effects of Radiation
 - (iv) Machine Safety
 - (I) Machine Functions
 - (II) Safety Procedures
 - (III) Recognizing Problems
3. Instruction required by .04(2)(a)2. shall begin within 30 days after employment and shall be completed no later than 90 days after date of employment. The registrant shall maintain a record of all training for each operator. Such record shall be made available for Departmental inspection. This rule shall take effect 180 days after the effective date of these regulations.

4. Persons who show written proof that they have received the required instruction are considered to meet the requirements of .04(2)(a)2.
- (b) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
 1. All individuals shall be positioned such that no part of the body will be struck by the useful beam, unless protected by at least 0.5 millimeter meter lead equivalent material; and
 2. Staff and ancillary personnel who must remain in areas because of their required presence during an x-ray procedure, shall be protected from direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent; and
 3. Patients, other than the one being radiographed, who cannot be removed from the x-ray room shall be protected by a barrier of at least .25 mm Pb equivalent or be at least 2 meters from the tube head and the image receptor.
 - (c) Except for dental intraoral radiography, veterinary, or portable x-ray use, the operator's position at the controls shall be in a protected area that will meet the radiation protection requirements of rule .03(2)(a)1. of these regulations.
 - (d) Except for therapy exposures, gonad shielding of not less than 0.25 millimeter lead equivalent shall be available and shall be used when the gonads are in the useful beam except when its use will interfere with the diagnostic information on the image receptor.
 - (e) Individuals shall only be exposed to the useful beam for healing arts purposes except as required by law enforcement officials or their designated representatives in the interest of public safety. This provision specifically prohibits deliberate exposure of persons for non-productive x-ray procedures such

as for training, demonstration, or for other non-healing arts purposes.

- (f) When a patient or film must be provided with auxiliary support during a radiation exposure:
 - 1. Mechanical holding devices shall be used when the technique permits. Holding shall be used only when other means of support cannot be utilized.
 - 2. No individual shall be used routinely to hold film or patients.
 - 3. When holding is required, the person holding shall be provided with protective clothing and shall be positioned so that no part of the body is struck by the useful beam.
- (g) Portable equipment shall be used only for examinations where it impractical, for medical purposes, to transfer the patient to the x-ray suite.

(3) Information and Maintenance Records and Associated Information.

- (a) The registrant shall maintain the following information for each radiation machine for inspection by the Department:
 - 1. Model and serial numbers of x-ray tube housing and generator; and
 - 2. Records of surveys, calibrations, maintenance, and modifications performed on the radiation machine(s) with the names of persons who performed such services.
- (b) The vendor shall supply the registrant with a record of all maintenance performed, or parts replaced or installed, written in a clear and legible manner.

(4) Light Fields. When used for aligning or centering an x-ray field, a light field shall have a clearly defined perimeter and have illumination intensity equal to the needs for collimation or alignment. For collimators equipped with beam defining lights, this requirement will be deemed to be met if the illumination at the receptor is visible to the x-ray operator under normal room illumination in all quadrants of the light field.

(5) Darkroom and Film Processors.

- (a) Darkrooms used for film processing and/or developing shall be light tight.
 - (b) Each darkroom shall be equipped with a safelight which will meet or exceed the requirements of the radiographic film. This will be deemed to have been met if the film manufacturer's recommendations are followed.
 - (c) Except for automatic developing systems, each darkroom shall have and use a solution thermometer and timing device. Sight development shall be prohibited.
 - (d) The chemical solution used for manual film development shall not be used for periods in excess of two (2) months. Records of solution changes shall be maintained.
 - (e) When automatic film processing is used it shall be maintained in accordance with the manufacturer's recommendations and a record of cleaning and developer change shall be maintained.
 - (f) Unexposed film shall not be subject to radiation levels in excess of 0.2 mR during the period of storage.
 - (g) Unexposed film which is outdated shall not be used for human radiographic procedures.
- (6) General Requirements for all Diagnostic Radiation Machines. In addition to other requirements of this part, all diagnostic radiation machines shall meet the following requirements:
- (a) Warning Label. The control panel containing the main power switch shall bear the following warning statement, in a manner 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 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 1 meter in any direction from the source, shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at its leakage technique factors.
- (d) Beam Quality.
 - 1. Half-value layer.
 - (i) The half-value layer of the useful beam for a given x-ray tube potential shall be no less than the values shown in Table I. If it is necessary to determine the half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (Kilovolts Peak)	Measured Potential (Kilovolts Peak)	Half-value layer (Millimeters of Aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50-70	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

- (ii) The requirements of .04(6)(d)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.

TABLE II

Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	Total Filtration
	(inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 to 70	1.5 millimeters
Above 70	2.5 millimeters

(iii) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

(iv) For capacitor energy storage equipment, compliance with the requirements of .04(6)(d)1. (i) shall be determined with the maximum quantity of charge per exposure.

(v) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

2. Filtration Controls. For radiation machines 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 .04(6)(d)1. (i) or (ii) is in the useful beam for the given kVp which has been selected.

(7) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

(8) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will

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remain stable during an exposure unless the tube housing movement is a designed function of the radiation machine.

- (9) Technique Indicators. The technique factors to be used during an exam shall be indicated prior to any exposure. This requirement may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(10) Exposure Timing.

- (a) Except in fluoroscopy a device shall be used to terminate and accurately reproduce 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.
- (b) Except for fluoroscopy, dental intraoral and panographic, veterinary, and procedures requiring the use of portable barriers, the exposure switch shall be so located that it cannot be conveniently operated outside of a shielded area.
- (c) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second.
- (d) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
- (e) Automatic exposure controls.
 - 1. When an automatic exposure control is provided, indication shall be made on the control panel when this mode of operation is selected.
 - 2. When an automatic exposure control is provided, a backup timer shall be required. The backup timer shall be capable of terminating the exposure at a preset time should the automatic exposure control fail. The preset time shall be consistent with the technique used.
- (f) The x-ray production shall be controlled by a deadman switch.

- (g) It shall not be possible to make an exposure when the time is set to a zero or off position if either position is provided.
 - (h) Termination of an exposure shall cause automatic resetting of the timing device to its initial setting or to zero.
- (11) Hand-held fluoroscopic screens are prohibited except for law enforcement or forensic requirements, and then only upon approval by the Department.
- (12) Fluoroscopic Radiation Machines. All fluoroscopic radiation machines shall meet the following requirements:
- (a) Limitation of Useful Beam.
 - 1. Primary Barrier.
 - (i) Image intensification shall be used with all fluoroscopic machines. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.
 - (ii) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier and image intensifier are in position to intercept the entire useful beam.
 - 2. X-Ray Field.
 - (i) For image-intensified fluoroscopic equipment, neither the length nor the width of the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.
 - (b) Spot film devices which are certified components shall meet the following additional requirements:
 - 1. Means shall be provided between the source and the patient for adjustment of the x-ray field size, in the plane of the film, to the size of that portion of the film which has been selected on the spot film selector; and

2. 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; and
 3. 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 2 percent of the SID.
- (c) Pre-certified fluoroscopic machines are exempt from the requirements of .04(12)(a) and .04(12)(b) provided that:
1. The machine was in service prior to the date of adoption of these regulations and meets all other applicable requirements for fluoroscopic machines. However, these machines shall be brought up to standards referenced in .04(12)(a) and (b) within three years from the date of adoption of these regulations or be taken out of service and electronically disabled.
 2. The shutter mechanism is adjusted so that the x-ray field diameter is limited to the dimensions of the film cassette used during spot filming at a 35 centimeters (14 inches) table-to-image-receptor distance.
 3. When spot films are either unnecessary or not required during a portion of the exam, the leading edge of the shutters shall be restricted to the edge of the image intensifier.
- (d) Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a dead man switch. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
- (e) Exposure Rate Limits.
1. Entrance Exposure Rate Allowable Limits.
 - (i) When the automatic brightness control is used, the exposure measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens per minute, except during recording of fluoroscopic images.

- (ii) When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.
 - (I) Special means of activation of high level controls shall be required. The high level control shall only be operable when a continuous secondary level of pressure is provided by the operator.
 - (II) When the high level control is activated the entrance exposure rate shall not exceed 10 R/min. except in the recording of fluoroscopic images.
 - (III) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
 - (iii) In addition to the other requirements of .04(12)(e)1. (i) and (ii), certified equipment which does not incorporate an 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 5 roentgens per minute at the point where the center of beam enters the patient, except during recording of fluoroscopic images or when provided with an optional high level control.
 - (iv) Non-certified equipment shall not operate at any combination of tube potential and current which will result in an exposure in excess of 10 R/min.
2. Compliance with the requirements .04(12)(e)1. shall be determined as follows:
- (i) Movable grids and compression devices shall be removed from the useful beam during the measurement;

- (ii) With the source below the table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle;
 - (iii) With the source above the table, the exposure rate shall be measured at 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;
 - (iv) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.
- (f) Periodic measurement of Entrance Exposure Rate. The registrant shall cause periodic measurement of entrance exposure rate, including the exposure rate at staff positions around the table and panel, to be made for each fluoroscope by an individual competent to make such measurements. Results of these measurements shall be posted where any fluoroscopist may have ready access to them. An adequate period for such measurements shall be annually or after any maintenance of the unit if such maintenance might affect the exposure rate. Results of the measurements shall include the maximum possible R/minute of the fluoroscope at the maximum kVp and mA used. The posted data shall indicate the technique factors used to determine the data along with the name of the person and/or company performing the measurements and the date the measurements were performed.
 - 1. Fluoroscopes 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 machine; and
 - 2. Fluoroscopes that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the radiation machine.
- (g) Barrier Transmitted Radiation Rate Limits. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly

beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

- (h) Indication of Potential and Current. During fluoroscopy and cine-fluorography, the kV and the mA shall be continuously indicated.
- (i) Source-Skin Distance. The source to skin distance shall not be less than:
 - 1. 38 centimeters (15 inches) on stationary fluoroscopes;
 - 2. 30 centimeters (12 inches) on all mobile fluoroscopes;
 - 3. 20 centimeters (8 inches) for image intensified fluoroscopes, used for specific surgical application;
 - 4. 30 centimeters (12 inches) on stationary precertified fluoroscopes.
- (j) Fluoroscopic Timer. Means shall be provided to preset the cumulative "on" time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. Termination of the exposure or 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 or until the timing device is reset. Audible signals are recommended.
- (k) Radiation Therapy Simulation Machines. Radiation therapy simulation shall be exempt from all the requirements of .04(12)(a), .04(12)(e), .04(12)(f) and of .04(12)(j) provided that:
 - 1. Such machines are designed and used so that no individual other than the patient is in the x-ray room during radiography procedures; and
 - 2. Such machines which do not meet the requirements of .04(12)(j) are provided with a means of indicating the cumulative exposure time for each individual patient. Procedures shall require in each case that the timer be reset between examinations.

(13) Radiographic Machines Other Than Fluoroscopic, Dental Intraoral, and Veterinary.

- (a) Beam Limitation. The useful beam shall be limited to the area of clinical interest, and shall not be greater than the dimensions of the image receptor.
- (b) General Purpose Stationary and Mobile Radiation Machines.
 - 1. Means for stepless independent adjustment in both the longitudinal and transverse direction of the x-ray field and a light for visually defining the perimeter of the x-ray field shall be provided.
 - 2. Means shall be provided to permit adequate light intensity at the film plane when the light field intersects with the image receptor at a 100 cm SID. This will be deemed to be met if a visual outline of the light field is visible at the receptor.
 - 3. Congruence of the x-ray and light fields shall not have a misalignment in excess of 2% of the SID in any one direction and not more than 3% of the SID when measured as the sum of the absolute misalignment in the longitudinal and transverse direction.
- (c) Additional Requirements for Stationary General Purpose Radiation Machines. In addition to the requirements of .04(13)(b), all stationary radiation machines shall meet the following requirements:
 - 1. Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the film plane with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent; and
 - 2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted.
- (d) Machines Designed for or Provided With Special Attachments for Mammography.
 - 1. Radiographic machines designed only for mammography and general purpose radiographic machines, 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 this edge by more than 2 percent of the SID.

2. This requirement can be met with a machine which performs as prescribed in .04(13)(e).
 3. 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.
- (e) Special Purpose Radiation Machines. Radiation machines which are limited by design to radiographic examinations of a specific anatomical region shall meet the following requirements:
1. The x-ray field in the plane of the image receptor shall be limited such that the field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor;
 2. The center of the x-ray field shall be aligned with the center of the image receptor to within 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 any edge of the image receptor;
 3. Section .04(13)(e)2. may be met with a machine that meets the requirements for a general purpose radiation machine as specified in .04(13)(b) or, when alignment means are also provided;
 4. For special purpose cephalometric use, an assortment of removable, fixed-aperture, beam-limiting devices sufficient to limit the beam to areas of clinical interest may be used. Each such device shall have clear and permanent markings to indicate the image receptor size and the SID for which it is designed;
 5. Special purpose radiographic units will be exempt from the primary barrier requirements of .01(8)(b)1. provided that the tube housing assembly is electronically

interlocked to a primary protective barrier, or the tube housing assembly is mechanically fixed such that the entire cross section of the useful beam is always intercepted by a primary barrier sufficient to attenuate the useful beam to the limits specified in .03(2). Secondary barriers shall meet the shielding requirements of .01(8)(b)1.

(f) Radiation Exposure Control Device.

1. Each x-ray control shall meet the following requirements:

- (i) stationary radiation machines shall have the exposure switch permanently mounted in such a way as to prevent the operator from leaving the protected area of the operator's barrier during the exposure;
- (ii) except for unique situations such as those found in intensive care units or operating room suites, mobile and portable radiation machines which are used for greater than 1 week in 1 location, (i.e., 1 room or suite) shall meet the requirements of .04(13)(f)1. (i).
- (iii) The x-ray control device shall provide audible or visual indication observable at or from the operator's protected position whenever x-rays are produced. For certified radiation machines, a signal audible to the operator shall indicate that the exposure has terminated.

2. Portable Equipment.

- (i) Provisions of .04(13)(f) apply except for exposure switch location.
- (ii) The exposure switch shall be so arranged that the operator can stand at least 1.8 meters (six feet) from the patient, the x-ray tube, and the useful beam unless there is shielding sufficient to assure compliance with .03(2)(a).
- (iii) The source-to-skin distance shall be limited to not less than 30 centimeters (12 inches).

- (iv) Protective aprons of at least 0.25 mm lead equivalent shall be available and their use shall be required of the operator.
- (v) Personnel monitoring is required of all operators.
- (vi) Mobile or portable Radiation machines which are used for greater than one week in one location, i.e., (one room or suite of rooms) shall meet the requirements of .01(8).

(g) Structural Shielding.

1. In addition to the requirements in .01(8), diagnostic radiation machines routinely used in one location shall meet the following requirements for structural shielding:
 - (i) All areas of the walls, floors, and ceiling exposed to the primary beam shall have primary barriers; and
 - (ii) Secondary protective barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers or where primary barrier requirements are less than secondary barrier requirements.
2. For stationary radiation machines and mobile or portable equipment routinely used in one location:
 - (i) Except for those unique situations found in such uses as the intensive care unit, operating suite, etc., the operator's station at the controls shall be behind a protective barrier which will intercept any radiation that has been scattered only once.
 - (ii) The operator's protective barrier shall be equipped with a glass window of lead equivalency equal to that required of the adjacent barrier, or a mirror system so placed that the entire patient can be seen by the operator while the exposure is made.
 - (iii) Facilities constructed or modified after the effective date of these regulations shall have built-in operator's protective barriers which will ensure that the limits specified in .03(2)(a) are not exceeded.

(h) Source-to-Skin Distance.

1. All radiographic machines, except as provided for in .04(13) (h)2., shall be provided with means to limit the source-to-skin distance to not less than 30 centimeters (12 inches).
 2. A radiographic machine intended for specific surgical and dental application may be used with an SSD less than 30 centimeters, (12 inches), but in no case less than 20 centimeters (8 inches).
- (i) Radiation From Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(14) Intraoral Dental Radiographic Machines.

- (a) Source-to-Skin Distance. Radiation machines designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, i.e., SSD, to not less than 18 centimeters (7 inches), if operable above 50 kVp, or 10 centimeters (4 inches), if not operable above 50 kVp.
- (b) Field Limitation.
1. Radiographic machines designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the diameter of the useful beam at the end of the cylinder shall not be greater than 7.0 centimeters (2.75 inches). For intraoral rectangular collimation the useful beam at the end of the spacer shall not have a diagonal measurement greater than 7.0 centimeters (2.75 inches). Positioning devices should be used to assure beam alignment.
 2. An open ended shielded cylinder, or other open ended shielded spacers that will meet the requirements of .04(14)(a) and (b)1. shall be used.
- (c) Structural Shielding.
1. The provisions of .01(8) shall apply, except that National Council on Radiation Protection and Measurements

Report No. 35, "Dental X-Ray Protection," or its current revision or replacement, shall be referenced by the Department.

2. When dental x-ray units are installed in adjacent rooms or areas, protective barriers sufficient to reduce the exposure to the requirements of .03(2) shall be provided between the rooms and/or areas.

(d) Operating Procedures.

1. Patient and film holding devices shall be used when the techniques permit.
2. Neither the tube housing nor the position indicating device shall be hand-held during an exposure.
3. Mechanical support of the tube head shall maintain the exposure position without drift.
4. Dental fluoroscopy shall not be used without image intensification and shall meet the requirements of .04(12).
5. Only persons required for the radiographic procedure shall be in the x-ray room during exposure. All persons shall be adequately protected.
6. The operator shall be able to view the patient during an exposure.
7. During each exposure, the operator shall stand at least 1.8 meters (6 feet) from the patient and tube head and outside the path of the useful beam or behind a barrier that meets the requirements of .03(2).

- (e) The total filtration in the useful beam shall not be less than the appropriate values stated in .04(6)(d)1. (i) or (ii).

(15) Veterinary Radiographic Installations.

(a) Equipment.

1. The tube housing shall be of the diagnostic type.

2. The primary beam for diagnostic purposes in radiography and fluoroscopy should not be larger than clinically necessary and shall not be greater than the image receptor. Cones, diaphragms, or adjustable collimators capable of restricting the primary beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required in the tube housing.
3. 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.
4. The exposure switch shall be of a dead-man type.
5. The total filtration permanently in the useful beam shall not be less than the appropriate value stated in .04(6)(d)1. (i) or (ii).
6. A means shall be provided for aligning the center of the x-ray beam with the center of the image receptor prior to an x-ray examination.
7. An easily discernible indicator which shows whether or not x-rays are being produced shall be on the control panel.
8. The installation shall be so arranged that the operator can stand at least six feet from the animal, the x-ray tube and out of the useful beam.
9. Leaded gloves and aprons shall be available for use, and shall be used by all personnel in the room during an exposure.
10. The effectiveness of protective equipment (i.e., gloves, aprons, etc.), shall not be impaired.

(b) Operating Procedures.

1. Only persons whose presence is necessary shall be in the radiographic area during exposure. Protective clothing of at least 0.25 mm lead equivalent shall be provided and shall be worn by all individuals required to be in controlled areas, except when the individuals are entirely

behind protective barriers while the equipment is energized.

2. Patient support:

- (i) When an animal patient or film must be held in position for radiography, mechanical supporting or restraining devices, or other means of immobilization, shall be used unless human holding is required by the technique.
- (ii) If an animal patient must be held or positioned manually, the individual holding the animal shall wear protective gloves having at least 0.5 mm lead equivalency and a protective apron of at least 0.25 mm lead equivalency;
- (iii) Personnel monitoring devices shall be used if radiation measurements indicate potential exposure in excess of 25 percent of the applicable values specified in Section .03(2)(a)1. to the head, or trunk of the body.

(c) Fluoroscopy.

- 1. The provisions of .04(12) shall apply to fluoroscopic equipment.

(d) Structural Shielding. The provisions of .01(8) shall apply except that the National Council on Radiation Protection and Measurements Report No. 36, "Radiation Protection in Veterinary Medicine," or its current revision or replacement, shall be referenced by the Department.

(16) Therapeutic Radiation Machines of Less Than One MeV.

- (a) Leakage Requirements. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified, at the distance specified for the classification of that radiation machine.
 - 1. Contact Therapy Machines. Leakage radiation shall not exceed 100 milliroentgens (.0258 mC/Kg) an hour at five (5) centimeters from the surface of the tube housing assembly.

2. 0-150 kVp Machines.
 - (i) Machines which were manufactured or installed prior to the date of adoption of these regulations shall not permit radiation leakage in excess of 1 Roentgen (.258 mC/Kg) in one (1) hour at one (1) meter from the source.
 - (ii) In machines manufactured on, or after the date of adoption of these regulations, leakage radiation shall not exceed 100 mR (.0258 mC/Kg) in one (1) hour at one (1) meter from the source.
 3. 151 to 999 kVp Systems. The leakage radiation does not exceed one (1) roentgen (.258 mC/Kg) in one (1) hour at one (1) meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam one meter from the source.
- (b) Permanent Beam Limiting Devices. The registrant shall be responsible for assuring that permanent fixed diaphragms or cones used for limiting the useful beam shall provide at least the same protection as required by the tube housing assembly.
- (c) Removable and Adjustable Beam Limiting Devices.
1. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful x-ray beam at the maximum kilovoltage and with maximum treatment filter.
 2. Adjustable beam limiting devices installed after the effective date of these regulations shall transmit not more than 1 per-cent of the useful x-ray beam.
 3. Adjustable beam limiting devices installed before the effective date of these regulations shall transmit not more than 5 per-cent of the useful x-ray beam.
- (d) Filter System.

1. The filter system shall be so designed that the filters cannot be accidentally displaced from the useful beam at any possible tube orientation; and
 2. The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/Kg) per hour under any operating conditions; and
 3. Each filter shall be conspicuously inscribed as to its material of construction and its thickness. For wedge filters, the wedge factor and wedge angle shall appear on the wedge or wedge tray.
- (e) Tube Immobilization. The tube housing assembly shall be capable of being immobilized during stationary treatments.
- (f) Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.
- (g) Timer.
1. A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and fractions of minutes.
 2. The timer shall have a preset time selector and an elapsed time indicator.
 3. The timer shall be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated.
 4. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to cycle the present time selector through zero time.
 5. The timer shall permit accurate presetting and determination of exposure times as short as 1 second.
 6. The timer shall not permit an exposure if set at zero.
 7. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

- (h) Control Panel Functions. The control panel, in addition to the displays required in other provisions of .04(16), shall have:
 - 1. an indication of x-ray production; and
 - 2. means for indicating kV and x-ray tube current; and
 - 3. means for terminating an exposure at any time; and
 - 4. a locking device which will prevent unauthorized use of the radiation machine; and
 - 5. for radiation machines installed after the date of adoption of these regulations, a positive display of specific filter(s) in the beam.
- (i) Source-to-Skin Distance. There shall be means of determining the SSD distance to within 1 centimeter.
- (j) Low Filtration X-Ray Tubes. Each radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.
- (k) Calibrations and Spot Checks.
 - 1. Calibrations.
 - (i) The calibration of therapeutic radiation machines shall be performed at intervals not to exceed 1 year and after any change or replacement of components which could cause a change in the radiation output.
 - (ii) The registrant shall insure that such calibration is performed by an individual competent to perform such work.
 - (iii) Records of calibrations performed shall be maintained by the registrant for at least 5 years after completion of the calibration.
 - (iv) A copy of the most recent radiation machine calibration shall be available at the control panel.
 - (v) The radiation machine shall not be used in the administration of radiation therapy unless the

calibrations required by .04(16)(k)1. (i)-(iv) have been met.

2. Spot Calibration Checks. Spot calibration checks on radiation machines capable of operation at greater than 150 kVp shall be performed in accordance with written procedures. A record of such checks shall be maintained for a two (2) year period after completion of the spot-check measurements.

(17) Additional Facility Design Requirements for Therapy Radiation Machines Capable of Operating Above 50 kVp and less than 1 MeV.

- (a) Voice Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(b) Viewing Systems.

1. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
2. When the primary viewing system is by electronic means, an alternate viewing system, which may also be electronic, shall be available for use in the event of electronic failure.
3. In the event of total failure of patient viewing, therapy shall be discontinued until the system is functioning.

(c) Structural Shielding. In addition to the provisions of .01(8):

1. For existing equipment operating above 125 kVp the required operator's barrier(s) shall be an integral part of the building;
2. For all therapeutic machines operating below 150 kVp, built or modified after the effective date of these regulations, the operator's barrier(s) shall be an integral part of the building;

3. For equipment operating above 150 kVp, the control panel shall be within a protective booth equipped with an interlocked door, or located outside the treatment room.
- (d) Additional Requirements for Radiation Machines Capable of Operation Above 150 kVp and less than 1 MeV.
1. All necessary shielding, except for any beam interceptor, shall be provided by fixed barriers;
 2. The control panel shall be outside the treatment room;
 3. All doors of the treatment room shall be electrically connected to the control panel such that x-ray production cannot occur unless all doors are closed;
 4. When the treatment room door is opened during any exposure, the exposure shall terminate immediately;
 5. After termination of the exposure, it shall be possible to restore the radiation machine to full operation only upon closing the door, and subsequently reinitiating the exposure at the control panel.
- (e) Operating Procedures.
1. Therapeutic radiation machines shall not be left unattended unless the machine is secured.
 2. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
 3. The tube housing assembly shall not be held by an individual during exposures.
 4.
 - (i) For radiation machines operating above 150 kVp, no individual other than the patient shall be in the treatment room during exposures.
 - (ii) For machines operating below 150 kVp, no individual other than the patient shall be in the treatment room unless such individual is protected by a barrier

sufficient to meet the requirements of these regulations.

(18) X-Ray and Electron Therapy Machines with Energies of One MeV and Above.

(a) Scope. This part applies to medical facilities using therapy machines with energies of 1 MeV and above. Additional requirements for these machines are found in Section ~~290-5-22~~ 111-8-90-.05 entitled "Radiation Safety Requirements for Particle Accelerators".

(b) Requirements for Equipment.

1. Leakage Radiation to the Patient Area.

(i) New equipment shall meet the following requirements:

(I) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters.

(II) For each machine, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in (.04)(18)(b)I. (i)(I) for the specified operating conditions. Records of leakage

radiation measurements shall be maintained for inspection by the Department.

- (ii) Existing equipment shall meet the following requirements:
 - (I) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of 2 meters radius centered on a perpendicular to the central axis of the beam 1 meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.
 - (II) For each machine, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in .04(18)(b)1. (ii)(I) for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the Department.

2. Leakage Radiation Outside the Patient Area for New Equipment.

- (i) The absorbed dose in rads (grays) due to leakage radiation except in the area specified in .04(18)(b)1. (i)(I) when measured at any point 1 meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in .04(18)(b)1. (i)(I).

- (ii) The registrant shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in .04(18)(b)2. (i) for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.
- 3. The registrant shall assure that adjustable or interchangeable beam limiting devices are provided and that such devices shall transmit no more than 2 percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. Documentation of the transmission factors shall be maintained at the facility for inspection by the Department. The neutron component of the useful beam shall not be included in this requirement.
- 4. Filters.
 - (i) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
 - (ii) For equipment manufactured after the effective date of these regulations which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:
 - (I) irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
 - (II) an interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - (III) a display shall be provided at the treatment control panel indicating the filter(s) in use;

- (IV) an interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
- 5. Beam Symmetry. In equipment manufactured after the effective date of these regulations, inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated. It shall be the registrant's responsibility to assure that the above requirements are met and that records of confirming tests are maintained for Departmental inspection.
- 6. Beam Monitors. All therapy accelerator machines shall be provided with radiation detectors in the radiation head.
 - (i) New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.
 - (ii) Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.
- 7. Selection and Display of Dose Monitor Units.
 - (i) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.
 - (ii) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

- (iii) After termination of irradiation, it shall be necessary to zero before subsequent treatment can be initiated.
 - (iv) For equipment manufactured after the effective date of these regulations, it shall be necessary after termination of irradiation to manually reset the preselected dose monitor units before irradiation can be initiated.
- 8. Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.
- 9. Termination of Irradiation by the Dose Monitoring System or Systems.
 - (i) Each of the required monitoring systems shall be capable of independently terminating irradiation.
 - (ii) Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.
 - (iii) If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitoring units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
- 10. Termination Switches. It shall be possible to terminate irradiation and equipment movements at any time from the operator's position at the treatment control panel.
- 11. Timer.

- (i) A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.
 - (ii) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
 - (iii) For equipment manufactured after the effective date of these regulations after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.
 - (iv) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.
12. Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:
- (i) Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
 - (ii) An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.
 - (iii) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - (iv) An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.

- (v) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.
 - (vi) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
13. Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:
- (i) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
 - (ii) An interlock system shall be provided to prevent irradiation if any selected operations to be carried out in the treatment room do not agree with those selected operations carried out at the treatment control panel.
 - (iii) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
 - (iv) For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.
14. Selection of Stationery Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:
- (i) Irradiation shall not be possible until a selection of stationery beam therapy or moving beam therapy has been made at the treatment control panel.
 - (ii) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.

- (iii) An interlock system shall be provided to prevent irradiation if any selected operations to be carried out in the treatment room do not agree with those selected operations carried out at the treatment control panel.
- (iv) The mode of operation shall be displayed at the treatment control panel.
- (v) For new equipment, an interlock system shall be provided to terminate irradiation if:
 - (I) movement of the gantry occurs during moving stationary beam therapy; or
 - (II) movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.
- (vi) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
 - (I) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.
 - (II) for new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.
- (c) Facility and Shielding Requirements. In addition to Section .01(8) of these regulations, the following design requirements shall apply:
 - 1. The treatment control panel shall be located outside the treatment room; and
 - 2. Except for entrance doors or beam interceptors, all the required barriers shall be fixed; and

3. Windows, mirrors, closed-circuit television, or other equivalent viewing devices shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. When the viewing system is by electronic methods, a secondary viewing system, which may also be electronic, shall be available for use in the event of failure of the primary system; and
4. Provision shall be made for two-way aural communication between the patient and the operator at the treatment control panel; and
5. The entrance to the treatment room shall be equipped with a steady, red warning light which operates when, and only when, radiation is being produced; and
6. Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.

(d) Calibrations and Spot Checks.

1. Calibration.
 - (i) A calibration of all new machines and existing machines not previously surveyed shall be performed prior to the initial irradiation of a patient and thereafter at time intervals not to exceed 12 months, and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. It shall be the responsibility of the registrant to ensure that the individual performing the calibration is competent to perform such calibrations.
 - (ii) The calibration of a particle accelerator machine shall be performed in accordance with a calibration protocol such as that published by the American Association of Physicists in Medicine in Volume 10, number 6, issue of Medical Physics, or its current revision or replacement.

- (iii) Any calibration protocol used must contain the following minimum measurement criteria:
 - (I) full calibration measurements shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.
 - (II) spot-check measurements shall be performed using a dosimetry system that has been calibrated in accordance with .04(18)(d)1. (iii)(I) of this rule. Alternatively, a dosimetry system spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with .04(18)(d)1. (iii)(I) of this rule. This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.
- (iv) The full calibration of the therapy beam shall include but not be limited to the following determinations:
 - (I) verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at the specified depth.
 - (II) the absorbed dose rate at various depths of water for the range of field sized used, for each effective energy, and for each treatment distance used for radiation therapy.

- (III) the uniformity of the radiation field and any dependency upon the direction of the useful beam.
- (IV) verification of depth-dose data and isodose curves applicable to the specific machine.
- (V) verification of transmission factors for all accessories such as wedges shadow trays, etc.
- (VI) records of full calibration measurements and dosimetry system calibrations shall be preserved for 5 years after completion of the full calibration.
- (VII) a copy of the latest full calibration performed as described in .04(18)(d)1. (iv)(I)-(VI) shall be available at the accelerator facility.

2. Spot-Calibration Checks.

- (i) Spot-calibration checks shall be performed on machines subject to .04(18)(b) during calibrations and thereafter at intervals not to exceed one month.
 - (ii) Such spot-calibration checks shall be in accordance with written procedures and shall include absorbed dose measurements in a phantom at intervals not to exceed one week.
 - (iii) Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check; and
 - (iv) Records of spot-check measurements performed pursuant to .04(18)(b) shall be maintained by the registrant for a period of 2 years after completion of the spot-check measurements and any necessary corrective actions.
- (e) Qualified Expert. The registrant shall determine if a person is an expert qualified by training and experience to calibrate a therapy machine and establish procedures for (and review the results of) spot-check measurements. The registrant shall determine that the person calibrating their therapy machine:

1. is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or x-ray and Radium Physics; or
 2. has the following minimum training and experience:
 - (i) a Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;
 - (ii) one year of full-time training in therapeutic radiological physics; and
 - (iii) one year of full-time experience in a radiotherapy facility including personal calibration and spot-check of at least one therapy machine.
- (f) Operating Procedures.
1. No individual other than the patient shall be in the treatment room during treatment of a patient.
 2. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.
 3. The machine shall not be used in the administration of radiation therapy unless the requirements of .04(18)(d) have been met.

Authority: Ga. L. 1964, pp. 507, 569, 570; O.C.G.A. Sec. 31-13-5.

Rule ~~290-5-22~~ 111-8-90-.05 Radiation Safety Requirements for Particle Accelerators

- (1) Scope. This section establishes procedures for the registration and use of particle accelerators for medical and non-medical applications. Additional requirements for medical accelerators are found in Section ~~290-5-22~~ 111-8-90-.04(18) entitled "Radiation and Electron Therapy Machines with Energies of one MeV and Above."
- (2) Registration Requirements. No person shall receive, possess, use, own, or acquire a particle accelerator except as authorized in the accelerator registration issued pursuant to these regulations. The

procedures for registration of particle accelerator facilities are included in these regulations.

- (3) General Requirements for the Issuance of a Certificate of Registration for Particle Accelerators. In addition to the requirements of .02(1), (2), (6), (7) and (8) of these regulations, the applicant shall submit a supplementary registration application for use of a particle accelerator. Registration will be approved only after the Department determines that:
 - (a) the applicant is responsible for the use of the accelerator;
 - (b) the applicant's proposed or existing equipment, facilities, operating and emergency procedures are adequate to protect health and minimize risk to public health and safety or property; and
 - (c) the issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in this section; and
 - (d) the applicant has appointed, for medical applications, a physician who is designated on the application as the radiation therapist and other such professional staff necessary to the safe operation and use of the accelerator.
 - (e) The applicant and/or the applicant's staff has experience in the use of particle accelerators and training sufficient for application to its intended uses; and
 - (f) The applicant has established a radiation safety committee (composed of one or more persons trained or experienced in the safe use of accelerators) to approve, in advance, proposals for uses of particle accelerators; and
 - (g) The applicant conducts training programs to assure continued competency for operators of particle accelerators; the protocol shall be in writing.
- (4) Human Use of Particle Accelerators. In addition to the requirements of .02 of these regulations, a registration for use of a particle accelerator in the healing arts will be issued only if:
 - (a) The applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of particle accelerator.

Membership of the committee shall include physicians expert in internal medicine, hematology, therapeutic radiology, and the radiological physicist.

- (b) The individuals designated on the application as the users are radiation therapists who have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans.

(5) Limitations.

- (a) No registrant shall permit any person to act as an operator of a particle accelerator until such person:
 - 1. has been instructed in radiation safety and in operating and emergency procedures; and
 - 2. has received copies of, and instruction in, the applicable requirements of these regulations; and
 - 3. has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in their assignment, and be able to demonstrate such knowledge to the Department upon request.
- (b) The radiation safety committee, radiological health physicist or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if any one of them deems such action is necessary to protect health and minimize danger to public health and safety or property.

(6) Shielding and Safety Design Requirements. Each particle accelerator installation shall be provided with such primary and/or secondary barriers as are necessary to assure compliance with .03(2)(a) and .03(2)(c) of these regulations. This requirement will be deemed to be met if the barriers are constructed in accordance with NCRP Report No.51.

(7) Particle Accelerator Controls and Interlock Systems.

- (a) Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

- (b) Except for portable accelerator, all entrances into a target room or other high radiation area shall be provided with interlocks. When access is gained through any entrance the accelerator shall shut down automatically.
- (c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting the tripped interlock and initiating starting up procedures at the main control console.
- (d) An emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.
- (e) Portable accelerators shall be exempt from .06(7)(b) provided that they are not used in one location in excess of 30 days.

(8) Warning Devices.

- (a) All locations designated as high radiation areas, and all entrances to such locations, shall be equipped with easily observable red warning lights that operate when, and only when, radiation is being produced.
- (b) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such a warning device shall be clearly discernible in all high radiation areas and all radiation areas.
- (c) Barriers, temporary or otherwise, and pathways leading to high radiation areas, shall be identified with caution signs, labels and signals in accordance with .03(4) of these regulations.

(9) Operating Procedures.

- (a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use;
- (b) The safety interlock system shall not be used to turn off the accelerator beam except in an emergency;

- (c) All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed one month. Results of such tests shall be maintained at the accelerator facility for inspection by the Department;
- (d) Electrical circuit diagrams of the accelerator and the associated interlock systems shall be kept current and available at each accelerator facility;
- (e) If, for any reason, it is necessary to intentionally by-pass a safety interlock or interlocks, such action shall be:
 - 1. authorized in writing by the radiation safety committee and/or radiation safety officer; and
 - 2. recorded in a permanent log and a notice posted at the accelerator control console; and
 - 3. terminated as soon as possible.
- (f) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel and shall include instructions in at least the following:
 - 1. the use of the accelerator in such a manner that no person is likely to be exposed to radiation doses in excess of the limits established in these regulations; and
 - 2. methods and occasions for conducting radiation surveys; and
 - 3. methods for controlling access to high radiation areas; and
 - 4. methods and occasions for locking the control panel of the accelerator; and
 - 5. personnel monitoring and the use of personnel monitoring equipment; and
 - 6. methods for minimizing exposure of individuals in the event of an accident; and
 - 7. the procedures for notifying appropriate persons in the event of an accident; and

8. the maintenance of records.

(10) Radiation Monitoring Requirements.

- (a) There shall be available at each particle accelerator facility, appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and/or repair.
- (b) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.
- (c) Facility shall have a written procedure concerning the conducting of area surveys and radiation protection surveys of the machine and facility shielding.
- (d) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility and made available for Departmental inspection.

(11) Ventilation Systems.

- (a) Means shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Chapter ~~290-5-23~~ 391-3-17 (Rules and Regulations for Radioactive Materials).
- (b) A registrant shall not vent, release or otherwise discharge airborne radioactive material to an uncontrolled area except as authorized pursuant to Chapter ~~290-5-23~~ 391-3-17.

Authority: Ga. L., 1964, pp. 507, 569, 570; O.C.G.A. Sec. 31-13-5.

Rule ~~290-5-22~~ 111-8-90-.06 Radiation Safety Requirements for the Use of Non-Medical X-Ray

- (1) Purpose. This section establishes the requirements for the non-healing arts use of x-rays.
- (2) Scope. This section applies to all non-healing arts radiographic, fluoroscopic, and analytical x-ray installations and any apparatus

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Presented to the BCH for Initial Adoption on 8/13/2020

capable of emitting x-rays as either a useful product or an unwanted by-product. The provisions of this section are in addition to and not in substitution for other applicable provisions of these regulations.

(3) General Provisions.

- (a) Each registrant shall provide personnel monitoring devices which are calibrated for the appropriate radiations and energies of radiation produced, and these devices shall be used by:
 - 1. Each individual who receives, or is likely to receive, a whole body dose in excess of 25 millirems per week; and
 - 2. Each individual who enters a high radiation area.
- (b) Each installation shall be provided with such primary protective barriers and/or secondary protective barriers as are necessary to assure compliance with section .01(8) and .03(2).
- (c) All areas in which radiation hazards may arise shall be identified by an appropriate and easily recognizable warning sign as described in .03(4).
- (d) Audible or visible signals shall be provided in the vicinity of installations to provide warning during irradiation and shall be activated prior to any exposure.
- (e) X-ray tubes shall be provided with protective housing(s) appropriate to the nature of the work to afford adequate protection to personnel. The housing(s) shall be at least equivalent to a therapeutic tube housing.
- (f) The operator or radiographer shall be provided with and shall have available for inspection a copy of normal operating and emergency procedures.
- (g) A key-operated primary control switch shall be provided such that x-ray production shall not be possible with the key removed.
- (h) Manufacturers of radiation machines shall provide for purchasers, and to the Department upon request, manuals and instructions which shall include at least the following technical and safety information:

1. potential, current, and duty cycle ratings of the x-ray generation equipment; and
 2. adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the machine; and
 3. a schedule of maintenance necessary to keep the machine in compliance with these regulations.
- (i) A suitable and functioning survey instrument, calibrated for the energy used, shall be at each installation.
- (j) Each entrance or access point to a high radiation area shall be:
1. equipped with a control device which shall cause the radiation generator to turn off automatically upon entry into the area; or
 2. maintained locked except during periods when access to the area is controlled.
- (k) Each high radiation area shall be arranged in such a way that an individual can quickly leave that area.
- (l) Tests of all devices such as interlocks, shutters, and warning lights shall be conducted at intervals not to exceed 3 months for all operable analytical x-ray equipment. Records of such tests shall be maintained for inspection by the Department.
- (4) Industrial Radiography.
- (a) Cabinet X-ray Installations.
1. The x-ray source and all objects exposed thereto must be contained within a permanent enclosure.
 2. All protective enclosures and equipment shall be kept in good repair.
 3. Radiation exposure shall not exceed 0.5 mR in any one hour at a distance of five centimeters (2 inches) from any point on the external surface of the cabinet or of any component outside the cabinet when operated under any conditions for which the machine is designed.

4. A control shall be provided that will enable the operator to initiate and terminate the production of x-rays by means other than the safety interlock system or main power control.
5. It shall not be possible to extend any part of the human body through a port into the primary beam.
6. Each door of a cabinet x-ray system shall have a minimum of two operative safety interlocks. One but not both of the required interlocks shall be such that a door opening results in physical disconnection of the energy supply circuit to the high voltage generator, and such disconnection shall not be dependent upon any moving part other than the door. The registrant shall:
 - (i) maintain records that verify the existence of dual interlocks.
 - (ii) maintain records of any repairs made on the dual interlocks; and -
 - (iii) certify to the Department that modifications have not been made to the dual interlocks that are not consistent with manufacturer's design specifications. Such certification shall be made to the Department with the application for registration, application for renewal of registration, and as a part of any inspection or investigation conducted by the Department. For purposes of inspection, the Department shall review these records and only that the cabinet x-ray system ceases x-ray production when the door is opened.
7. For cabinet x-ray systems designed for entry by an individual during the normal course of use of the machine, there shall also be provided:
 - (i) Audible and visible warning signals within the cabinet which must be activated for at least 10 seconds immediately prior to the first initiation of x-radiation production; and
 - (ii) A visible signal within the cabinet which shall remain operative for the duration of x-ray production. It

shall be automatically initiated prior to x-ray production and terminated with the exposure; and

- (iii) Suitable means of egress, so that any person may escape the interior of the cabinet without delay, or an effective means within the cabinet for preventing or terminating production of the x-radiation, and which cannot be reset from the outside of the cabinet.

- 8. Following interruption of x-ray generation by operating any interlock, the resumption of x-ray generation shall be possible only from the control panel.

(b) Shielded Room Radiographic Installations.

- 1. Facilities utilizing shielded room radiography shall assure that:
 - (i) Radiation levels at any point on the exterior of the room do not exceed those specified in .03(2)(c); and
 - (ii) All the requirements specified in .06(4)(a)7. shall apply.
 - (iii) Each door of a shielded room shall have a minimum of two operative safety interlocks. One but not both of the required interlocks shall be such that a door opening results in physical disconnection of the energy supply circuit to the high voltage generator.

(c) Open X-ray Installations.

- 1. Radiation areas in excess of 5 mR/hr shall be identified. A fence, rope or other suitable personnel barrier shall be erected along a 5 mR/hr, or less, contour line.
- 2. The area described by the temporary barricade shall be suitably posted with caution signs.
- 3. Suitable personnel monitoring devices for the energy used shall be provided and shall be used by persons in the area. One device shall be a cumulative direct reading device, the other a film badge, or equivalent.

4. During each radiographic operation, either the radiographer or an assistant shall maintain direct vigilance of the operation to insure against unauthorized entry into the radiation area.
5. All persons shall be removed from the radiation area before irradiation is begun.
6. The radiation machine itself, or the place in which the machine is stored, shall be locked in order to prevent unauthorized use.
7. Written records of personnel exposure, safety procedures and scaled drawing of the 5 mR/hr contour line shall be at the work site.
8. Each facility shall have a suitable and functioning survey instrument.

(5) Analytical X-Ray.

(a) Equipment.

1. The leakage radiation from the tube housing shall not exceed a radiation level of 25 milliroentgens in 1 hour at 5 centimeters (2 inches) from the surface of the tube housing at any specified tube rating.
2. Radiation originating within the high voltage power supply (i.e., transformer and rectifiers) shall not exceed a radiation level of 0.5 milliroentgen in one 1 hour at every specified rating at a distance of 5 centimeters (2 inches) from the housing of the power supply.
3. For open beam x-ray equipment:
 - (i) Sufficient warning lights or other equally conspicuous signals that operate only when the primary x-ray beam is released from the beam ports shall be provided in such a manner as to alert individuals to the potential radiation hazard. These signals shall be labeled so that their purpose is easily identified.
 - (ii) The operator shall be in immediate attendance at all times when the equipment is in operation except

when the area is locked to protect against unauthorized or accidental entry.

- (iii) When not in use, equipment shall be secured in such a manner as to be inoperable by unauthorized persons.
 - (iv) Each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator, or a coupling and recording device with beam absorber, has been connected to the port.
- 4. The radiation level for analytical x-ray equipment in which the primary x-ray beam is completely enclosed shall be less than 2 milliroentgens in ~~one~~ 1 hour at 25 centimeters (10 inches) from the apparatus at every specified tube rating.
 - 5. Each analytical system shall be so arranged as to restrict the entry of parts of the body into the primary beam. This may be accomplished by using such arrangements as adequate barriers or interlocks.
 - 6. The analytical x-ray device shall be provided with a protective barrier which absorbs the useful beam behind the specimen under examination.
 - 7. In addition to any other signs or labels required, a sign or label shall be placed on or adjacent to each x-ray tube housing and shall be located as to be clearly visible to any individual who may be working in close proximity to the primary beam path. The sign or label shall read:
"CAUTION - HIGH INTENSITY X-RAY BEAM."
 - 8. A warning light with the notation "X-RAY ON," shall be located on the control panel and:
 - (i) shall light only when the x-ray tube is activated; and
 - (ii) shall be wired in series with the primary electrical circuit so that if the warning light is inactivated x-ray generation is not possible.

9. The coupling between the x-ray tube and the collimator of the diffractometer, camera, or other accessory shall prevent radiation from escaping the coupling.
10. All tube head ports which are not in use shall be secured in the closed position in a manner which will prevent casual opening. Port covers shall offer the same degree of protection as is required of the tube housing.

(b) Operation of Equipment.

1. The registrant shall not permit the routine operation of any equipment that would require an individual to expose any part of his body to the primary beam.
2. Written operating and emergency procedures pertaining to radiation safety shall be established for each facility and shall be posted in a conspicuous location near each unit of analytical x-ray equipment.
3. Only qualified personnel shall be permitted to install, repair or make modifications to the x-ray generating apparatus and the tube housing-apparatus complex.
4. Any temporary alteration to safety devices, such as bypassing interlocks or removing shielding shall be:
 - (i) prohibited during normal operation of the equipment;
 - (ii) specified in writing and posted near the x-ray tube housing so that other individuals will know the existing status of the x-ray apparatus; and
 - (iii) terminated as soon as possible; and
 - (iv) recorded and the record maintained for inspection by the Department. This record should contain such information as date alteration was made, type of alteration, length of time unit remained in the altered condition, and signed by the individual who restored the unit to original condition.
5. Interlocks shall not be used to deactivate the x-ray tube except in an emergency or during testing of the interlock

system; it shall be possible to restore the machine to full operation only from the control panel.

6. Safety glasses shall be provided and required for use by operators, assistants, and maintenance personnel. Personnel monitoring in the form of ring badges or the equivalent should be utilized.

(c) Surveys. Radiation surveys of all analytical radiation machines shall be performed:

1. following any change in the initial arrangement, number, or type of components in the machine; or
2. following any maintenance requiring the disassembly or removal of a component in the machine; or
3. during the performance of maintenance and alignment procedures, if the procedures require the presence of a primary x-ray beam when any component in the machine is disassembled or removed; or
4. any time a visual inspection of the local components in the machine reveals an abnormal condition; and
5. It shall be the responsibility of the registrant to ensure that such radiation surveys are performed by an individual competent to perform such surveys.

(d) Medical Examination. Operators and personnel routinely assisting in analytical x-ray operation or maintenance shall be instructed regarding the potential physical hazards of such an x-ray beam. They shall be required to report any evidence of accidental physical injury or accidental exposure to radiation to the individual in charge of radiation protection. That person shall require immediate medical examination of the suspected injury and, if such injury has occurred, shall notify the Department by telephone and in writing within 24 hours.

(6) Non-Medical Fluoroscopy.

(a) Industrial Use:

1. In addition to the applicable provisions of this section .06, provisions shall be made to maintain adequate protection

when manipulating or marking objects under examination.

2. "Hand-held" fluoroscopes shall not be used.
 3. The exposure rate due to transmission through the image receptor shall not exceed 2 mR/hr at a distance of 10 centimeters (4 inches) from any point on the receptor.
 4. The maximum x-ray dose shall not exceed 0.5 mR in any one hour measured at 5 centimeters (2 inches) from any readily accessible machine surface.
 5. A method of dosimetry for these systems shall be employed which shall quantitatively define, with an accuracy of + 20 percent, the x-ray dose within the energy range of 30-150 kVp. Any method of film dosimetry, thermoluminescent dosimetry, or electronic instrumentation which shall be capable of this measurement will be acceptable.
 6. Any installation for baggage surveillance shall be enclosed and so designed as to prohibit ready access to x-ray generating equipment.
 7. It shall not be possible to insert any part of the body into the primary beam.
 8. The control panel shall be equipped with a key lock. It shall not be possible to remove the key in the "on" position.
 9. A positive pressure switch shall be provided to control the exposure and shall be located such that the operator has a clear view of the radiation machine.
- (b) Non-Controlled Areas. Personnel dose limits shall not exceed 10 mR in any one week or 500 mR in any one year.
- (7) X-Rays As Unwanted By-Product.
- (a) All equipment in which electrons are accelerated to an energy in excess of 5 keV shall be regarded as a potential source of ionizing radiation, such as: electron microscopes, cathode-ray tubes, television and imaging tubes.

- (b) All such equipment shall be constructed, installed and operated in such a manner as to provide adequate protection according to these regulations.
 - (c) Such items of equipment shall be shielded and provided with interlocks so as to ensure that the places where they are used can be regarded as being outside "controlled areas."
 - (d) The dose rate at any readily accessible point 5 centimeters (2 inches) from the surface of such equipment shall not exceed 0.5 mR/hr.
- (8) Instruction of Personnel.
- (a) The registrant shall assure that all radiation machines and associated equipment under his control is operated only by individuals instructed in safe operating procedures and competent in the safe use of the equipment. The registrant shall also assure that persons operating his radiation machine and associated equipment have received, at a minimum, two hours of instruction in the following six (6) subject categories:
 - 1. Fundamentals of Radiation Safety:
 - (i) Characteristics of radiation
 - (ii) Units of radiation measurement
 - (iii) Significance of radiation dose and exposure
 - (I) Radiation protection standards
 - (II) Biological effects of radiation
 - (iv) Sources and levels of radiation
 - (v) Methods of controlling radiation dose
 - (I) Working time
 - (II) Working distances
 - (III) Shielding
 - 2. Radiation Detection Instrumentation to be Used:

- (i) Use of radiation survey instruments
 - (I) Operation
 - (II) Calibration
 - (III) Limitations
 - (ii) Survey techniques
 - (iii) Use of personnel monitoring equipment
 - (I) Film badges
 - (II) Thermoluminescent dosimeters
 - (III) Pocket dosimeters
3. Radiographic Equipment to be Used:
 - (i) Remote handling equipment
 - (ii) Radiographic exposure devices and sealed sources
 - (iii) Operation and control of x-ray equipment
 4. The Requirements of Pertinent Federal and State Regulations.
 5. The Registrant's Written Operating and Emergency Procedures.
 6. Case Histories of Radiography Accidents.
- (b) Training shall begin within 30 days after employment and shall be completed no later than 90 days after date of employment. The registrant shall maintain a record of all training for each operator. Such record shall be made available for Departmental inspection.

Authority: Ga. L., 1964, pp. 507, 569, 570; O.C.G.A. 31-13-5.

Rule ~~290-5-22~~ 111-8-90-.07 Records, Reports and Notifications

- (1) Records and Reports.

- (a) Each registrant shall maintain records, in the same units used in this chapter, showing the radiation exposures of all individuals for whom personnel monitoring is required under these regulations. Such records shall be kept on Department forms, in accordance with the instructions contained in that form or in a clear and legible manner containing all the information required on the Department forms. The doses entered on the forms or records shall be for periods of time not exceeding one calendar quarter.
- (b) Each registrant shall maintain records, in the same units used in this chapter, showing the results of surveys, safety checks and calibrations required under these regulations.
- (c) Records of individual radiation exposure which must be maintained pursuant to the provisions of .07(1)(a) of this Chapter shall be preserved until a date five (5) years after termination of the individual's employment or association with the registrant, or such other time as the Department may determine.
- (d) The discontinuance or curtailment of activities does not relieve the registrant of responsibility for retaining all records required by this section.
- (e) The Department may require further preservation of records which it determines shall not be destroyed. Records which must be maintained pursuant to this section may be maintained in the form of microfilm.
- (f) Each person who possesses a radiation machine shall keep records showing the receipt, transfer, or disposal of such radiation machine and shall make such records available for inspection by the Department upon request.
- (g) The registrant shall keep a record of all major maintenance and/or modifications performed on each radiation machine during the period it is under his control. Such record shall be transferred to any subsequent owner of the equipment. Records shall include, but not be limited to, tube housing or x-ray tube insert replacement, any re-orientation of the machine, repair or change of the console or high-voltage supply, or collimator repair.

(2) Notification of Incidents.

- (a) Immediate Notification. Each registrant shall immediately notify the Georgia Department of ~~Human Resources~~ Community Health, Radiological Health Section, Atlanta, Georgia, by telephone and confirming letter of any incident involving any source of radiation possessed by him which may have caused exposure of the whole body of an individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual to 150 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms of any individual to 375 rems or more of radiation.
 - (b) Twenty-four Hour Notice. Each registrant shall within 24 hours notify the Georgia Department of ~~Human Resources~~ Community Health, Radiological Health Section, by telephone and confirming letter of any incident involving any source of radiation possessed by him which may have caused exposure of the whole body of any individual to 5 rems or more of radiation; exposure of the skin of the whole body of any individual to 30 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms to 75 rems or more of radiation.
 - (c) Special Requirements for Reporting. Any report filed with the Department pursuant to .07(2) shall be prepared in such a manner that names of individuals who have received exposure to radiation will be stated in a separate part of the report.
- (3) Report ~~To~~ Former Employees and Others of Exposure to Radiation. A registrant, at the request of any individual formerly employed or associated with such registrant (e.g., student, craftsman, etc.), shall furnish to such individual a report of his exposure to radiation as shown in records maintained pursuant to .07(1)(a). Such report shall be furnished within 30 days from the time the request is made and shall cover each calendar quarter of the individual's employment or association involving exposure to radiation, or such lesser period as may reasonably be requested by the individual. The report shall be in writing.
- (4) Reports of Overexposures and Excessive Levels.
- (a) In addition to any notification required by .07(2), each registrant shall make a report in writing within 30 days to the Georgia Department of ~~Human Resources~~ Community Health, Radiological Health Section, of:

1. Each exposure of an individual to radiation in excess of any applicable limit set forth in these regulations.
 2. Levels of radiation (whether or not involving excessive exposure of any individual) in an uncontrolled area in excess of 10 times any applicable limit set forth in these regulations.
- (b) Each report required under .07(4)(a) shall describe the extent of exposure of individuals to radiation, levels of radiation involved, the cause of the exposures, and corrective steps taken or planned to assure against a recurrence.
 - (c) In any case where a registrant is required to report to the Department any exposure of an individual to radiation, the registrant shall, no later than the making of such report to the Department, also notify the individual of the nature and extent of exposure.
 - (d) Any report filed with the Department pursuant to this paragraph shall be prepared in such a manner that names of individuals who have received exposure to radiation will be stated in a separate part of the report.
- (5) Notice to Employees. Each registrant shall annually advise any individual employed or associated with such registrant of the individual's exposure to radiation as shown in records maintained by the registrant pursuant to .07(1)(a), if requested by the individual.
 - (6) Instruction of Personnel, Posting of Notices to Employees.
 - (a) Each registrant shall advise individuals working in a restricted area of reports of radiation exposures which individuals may request in accordance with these regulations.
 - (b) Any Department documents or instructions sent to the registrant shall be maintained with a current copy of these regulations or posted as required.

Authority: Ga. L., 1964, pp. 507, 569, and 570, O.C.G.A. Sec 31-13-5, 31-13-9.

Rule 290-5-22 111-8-90-.08 Penalties

- (1) Any registrant who violates the provisions of O.C.G.A. Section 31-13-14, or who hinders, obstructs, or otherwise interferes with any representative of the Department in the discharge of official duties in making inspections as provided in O.C.G.A. Section 31-13-5, or in impounding materials as provided in O.C.G.A. Section 31-13-11, shall be guilty of a misdemeanor.
- (2) Any registrant who:
 - (a) Violates any registration provision of Chapter 13 of Title 31 of the Official Code of Georgia Annotated; or any rule, regulation, or order issued thereunder; or any term, condition, or limitation of any registration certificate thereunder; or commits any violation for which a registration certificate may be revoked under this Chapter may be subject to a civil penalty to be imposed by the Department. If the violation is a continuing one, each day of such violation shall constitute a separate violation for the purpose of computing the applicable civil penalty.
- (3) Imposition of such civil penalties shall relate to the severity of the violations.
 - (a) Users are subject to civil penalties not to exceed \$1,000 for violations that cause or contribute to the exposure of any persons or the environment to radiation levels in excess of those levels set forth in these rules. Violations which cause or contribute to such exposure are:
 1. Failure of registrant to take action in a timely manner to correct unsafe conditions or equipment of which it was aware or should have been aware;
 2. Use of untrained, unskilled, or unauthorized operators/users;
 3. Lack of, or failure to follow safety procedures;
 4. Unauthorized or improper modifications to machines or other radiation sources or equipment containing such sources; and
 5. Lack of sufficient radiation shielding to prevent excessive radiation exposure.

- (i) For purposes of computing the penalty, each day of such violation is a separate violation.
- (b) Users are subject to civil penalties not to exceed \$500 for other violations, to wit violations that do not cause or contribute to excessive exposure.
 - 1. For purposes of computing the penalty, each day of such violation is a separate violation.
- (c) Users that fail to register in accordance with rule .02(1) of this Chapter are subject to civil penalties not to exceed \$1000.00.
 - 1. For purposes of computing the penalty, each day of such violation is a separate violation.
- (d) In proposing the imposition of civil penalties, the Department shall consider such mitigating circumstances as it deems appropriate. These may include factors such as elapsed time of the violation, the registrant's prior compliance history, or voluntary reporting of the violation by the registrant.
- (4) Whenever the Department proposes to subject a registrant to the imposition of a civil penalty, it shall notify such registrant in writing:
 - (a) Setting forth the date, facts, and nature of each act or omission with which the person is charged;
 - (b) Specifically identifying the particular provision or provisions of the Code section, rule, regulation, order, or registration involved in the violation; and
 - (c) Advising of each penalty which the Department proposes to impose and its amount.
 - (d) Such written notice shall be sent by registered or certified mail by the Department to the last known address of such person. The person so notified shall be granted an opportunity to show in writing, within ten days from receipt of such notice, why such penalty should not be imposed. The notice shall also advise such registrant that, upon failure to pay the civil penalty subsequently determined by the Department, if any, the penalty may be collected by civil action.
 - (e) Upon receipt of a written response from the registrant alleging that a penalty should not be imposed, the

Department shall consider the response and make a final decision on the appropriateness and amount of the penalty. The Department may at its discretion conduct an onsite inspection in order to make a final decision. In making this decision, the Department may, as deemed appropriate by the Department, consider such factors as: errors concerning the amount or nature of the penalty, corrective action taken by the registrant, or disposal of machines or equipment by the registrant.

- (f) The Department shall inform the registrant of its final decision by registered or certified mail to the last known address of the registrant. Within 10 days of receipt of the Department's final determination concerning the civil penalty, the registrant may request an appeal pursuant to the Georgia Administrative Procedures Act, O.C.G.A. 50-13-1, et seq.

Authority: Ga. L. 1964, pp. 507, 569, and 570; O.C.G.A. Sec. 31-13-15.

Rule ~~290-5-22~~ 111-8-90-.09 Enforcement

- (1) The administration and enforcement of these rules shall be as prescribed in ~~Chapter 5 of Title 31 of the Official Code of Georgia Annotated~~, Chapter 13 of Title 31 of the Official Code of Georgia Annotated, and Chapter 13 of Title 50 of the Official Code of Georgia Annotated. The Department's action revoking or denying a registration applied for under this Chapter or the imposition of civil penalties imposed pursuant to this Chapter shall be preceded by notice and opportunity for a hearing and shall constitute a contested case within the meaning of Chapter 13 of Title 50 of the Official Code of Georgia Annotated.
- (2) The Department may, without regard to the availability of other remedies, including administrative remedies, seek an injunction against the continued operation of an unregistered radiation machine or the continued operation of a radiation machine in violation of this Chapter or of any regulation of the Department.

Authority: O.C.G.A. Secs. 31-13-5, 31-13-15.