420-3-26-.09 Radiation Safety Requirements For Users Of Particle Accelerators

(1) **Scope**. Rule 420-3-26-.03 establishes standards for the use of all radiation sources. The provisions of this Rule 420- 3-26-.09 are in addition to, and not in substitution for, other applicable provisions of these rules.

(2) **Definitions**.

(a) "Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

(b) "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

(c) ñAcceleratorò 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. For purposes of this definition, ñparticle acceleratorò, ñlinear acceleratorò and ñcyclotronò are equivalent terms.

(d) ñAgencyò means the Alabama State Board of Health.

(e) "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

(f) ñAuthorized medical physicistò means an individual who meets the requirements of Rule 420-3-26-.08(10)(a)3. and 4.

(g) ñAuthorized userò means a practitioner of the healing arts who meets the requirements of Rule 420-3-26-.08(10)(a)2.and 4.

(h) "Barrier" see "Protective barrier."

(i) ñBeam scatter filterò means a filter used in order to scatter a beam of electrons.

(j) ñCentral axis of the beamò means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

(k) ñDose monitoring systemò means a system of devices for the detection, measurement, and display of quantities of radiation.

(l) ñDose monitor unitò means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

(m) ñEmergency proceduresò means the written preplanned steps to be taken in the event of, or the potential for actual or suspected, unplanned exposure of individuals to radiation. This procedure should include the names and telephone numbers of individuals to be contacted as well as directives for processing the film badge or other personnel monitoring device.

(n) ñField sizeò means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance, and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

(o) ñGantryò means that part of the system supporting and allowing possible movements of the radiation head.

(p) "Half-value layer (HVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

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

(r) "Intensity Modulated Radiation Therapy (IMRT)" means radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer-based optimization techniques.

(s) ñInterlockò means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

(t) ñInterruption of Irradiationò means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(u) "Irradiation" means the exposure of a living being or matter to ionizing radiation.

(v) ñIsocenterò means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.

(w) "Kilovolt (kV) [kilo electron volt (keV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum.

(x) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.

(y) "Light field" means the area illuminated by light, simulating the radiation field.

(z) "mA" means milliampere.

(aa) "Megavolt (MV) [mega electron volt (MeV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum.

(bb) ñMisadministrationò means the administration of a Therapeutic Particle Accelerator Dose:

1. Involving the wrong patient, wrong treatment modality or wrong treatment site; or

2. When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent (30%); or

3. When the calculated total administered dose differs from the total prescribed dose by more than twenty percent (20%) of the total prescribed dose.

(cc) ñMoving beam radiation therapyò means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

(dd) "Nominal treatment distance" means:

1. for electron irradiation, the distance from the scattering foil, virtual source or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. for x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

(ee) ñOperating proceduresò means detailed written instructions including, but not limited to, the normal operation of movable shielding, closing of interlock circuits, manipulation of accelerator controls, radiation monitoring procedures, wearing of dosimeters, testing of interlocks, and record keeping requirements.

(ff) ñOperatorò means a person qualified by training and experience to assume responsibility for the safe operation of a particle accelerator.

(gg) ñPeriodic quality assurance checkò means a procedure which is performed to ensure that a previous parameter or condition continues to be valid.

(hh) ñPersonnel monitoring equipmentò means devices designed to be worn or carried by an individual for the purpose of measuring the dose received such as film badges and pocket dosimeters.

(ii) ñPhantomò means an object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

(jj) ñPrescribed doseò means the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

(kk) ñPrimary dose monitoring systemò means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitoring units have been delivered.

(ll) ñProtective Barrierò means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

1. ñPrimary protective barrierò means the material, excluding filters, placed in the useful beam.

2. ñSecondary protective barrierò means the material which attenuates stray radiation.

(mm) ñRadiation areaò means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (5 millirems) (0.05 mSv) in one (1) hour at 30 centimeters from the radiation source or from the surface that the radiation penetrates.

(nn) ñRadiation headò means the structure from which the useful beam emerges.

(oo) ñRadiographerò means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the registrant for assuring compliance with the requirements of these rules and all conditions of the registration.

(pp) ñRedundant beam monitoring systemò means a combination of two independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

(qq) ñScattered radiationò means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

(rr) ñSecondary dose monitoring systemò means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

(ss) ñShadow trayò means a device attached to the radiation head to support auxiliary beam limiting material.

(tt) ñStationary beam therapyò means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

(uu) ñTargetò means that part of a radiation head which, by design, intercepts a beam of accelerated particles with subsequent emission of other radiation.

(vv) ñTermination of irradiationò means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(ww) ñUseful Beamò means the radiation emanating from the tube housing port or the radiation head and passing though the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic machine to produce radiation.

(xx) ñVisiting authorized medical physicistò means a medical physicist who meets the requirements of Rule 420-3-26-.08(10)(a)6.

(yy) ñVisiting authorized userò means an authorized user who meets the requirements of Rule 420-3-26-.08(10)(a)5.

(zz) ñVirtual sourceò means a point from which radiation appears to originate.

(aaa) ñWedge filterò means a filter which effects continuous change in transmission over all or part of the useful beam.

(bbb) ñWritten directiveò means an order in writing for the administration of radiation to a specific patient or human research subject as specified in 420-3-26-.09(8)(j).

(3) **Records**. In addition to the records required elsewhere in these rules, each registrant shall maintain records of any tests or surveys required by this Rule 420-3-26-.09.

(4) **General Safety Provisions**.

(a) The Agency may waive compliance with the specific requirements of this Part by an existing machine or installation if the registrant demonstrates, to the Agency's satisfaction, achievement through other means of radiation protection equivalent to that required by these rules.

(b) Personnel Monitoring. Each registrant shall provide personnel monitoring devices which shall be calibrated for the appropriate radiations and energies of radiation produced by the particle accelerator and shall be used by:

1. Each individual who receives, or is likely to receive, a whole body dose in excess of 10 millirems per week; and,

2. Each individual who enters a high radiation area.

(c) Shielding.

1. Each installation shall be provided with such primary protective barriers and/or secondary protective barriers as are necessary to assure compliance with 420-3-26-.03(6), 420-3-26-.03(12), 420-3-26-.03(13), and 420-3-26-.03(14) of these rules. All protective barriers shall be fixed except for entrance doors or beam interceptors.

(d) Controls and Safety Devices.

1. Only the particle accelerator operator at the control panel located outside the shielded room shall be capable of turning on particle accelerator beams that are capable of producing exposure rates in excess of two (2) millirems per hour.

2. All entrances into a target room, treatment room, or other high radiation areas shall be provided with safety interlocks that shut down the machine under conditions of barrier penetration.

3. Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.

4. When any interlock is interrupted, broken, or tripped, either the particle accelerator will shut off automatically or the radiation level within the room will be reduced to less than two (2) millirems per hour at a distance of one (1) meter in any direction from any

accessible portion of the particle accelerator system.

5. Interlocks shall not be used to routinely shut off the particle accelerator.

6. An emergency cut-off switch shall be located in all high radiation areas. This switch shall be readily identifiable. This switch shall be capable of automatically causing the particle accelerator to either shut off or reduce the radiation level to less than two (2) millirems per hour at a distance of one (1) meter in any direction from any accessible portion of the particle accelerator system. Such cut-off switch shall include a manual reset at each such switch which must be reset at the switch before the particle accelerator may be restarted by the operator at the control panel. Radiation levels produced by radioactive materials shall not be considered as the radiation levels to be reduced.

7. All locations designated as high radiation areas shall be equipped with easily observable flashing or rotating warning lights and/or audible warning devices that operate when, and only when, radiation is being produced. Each entrance to such area shall have a visual warning device, which need not be flashing or rotating, that operates when and only when radiation is being produced.

8. Except for 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 a high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

9. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 420-3-26-.03 of these rules.

10. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

11. The particle accelerator control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, make the particle accelerator incapable of producing any area in which radiation exposure is in excess of two (2) millirems per hour.

12. There shall be available at each facility, appropriate portable radiation monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced by the facility. Such equipment shall be tested for proper operation daily and calibrated for the appropriate radiations at intervals not to exceed one (1) year and after each instrument servicing and repair.

13. There shall be present at the control panel a device which shall give a continuous indication of the radiation levels being produced in the target area or areas.

14. Radiation levels in all high radiation areas shall be continuously monitored. The

monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

15. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

16. Electrical circuit diagrams of the accelerator and the associated interlock systems shall be kept current and maintained for inspection by the Agency and shall be available to the operator at each accelerator facility.

(e) Operation.

1. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

2. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency, or to test interlocks.

3. Interlocks may be prevented from operation only to test, adjust, maintain, and/or rearrange equipment provided a clear indication of such condition is made at the control panel. This paragraph does not authorize the operation of a particle accelerator with the high radiation area warning devices incapable of proper operation.

4. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(i) Authorized in writing by the radiation safety committee or the radiation safety officer;

(ii) Recorded in a permanent log and a notice posted at the accelerator control console; and

(iii) Terminated as soon as possible.

5. No individual shall be permitted to enter an area, access to which is controlled by interlocks, while such interlocks are prevented from operation, to test, adjust, maintain, and/or rearrange equipment and/or parts of the particle accelerator unless such individual is utilizing appropriate personnel monitoring equipment which will give an audible indication when a dose-rate of 25 millirem per hour is exceeded. The personnel monitoring equipment referred to in this paragraph is in addition to that required elsewhere in these rules.

(5) **Operator Training**.

(a) No registrant shall permit any person to act as an operator as defined in this Rule 420-3-26-.09 until such person;

1. Has been instructed in the subjects outlined in Appendix A of this Rule 420-3-26-.09 and shall have demonstrated understanding thereof;

2. Has received copies of and instruction in the rules contained in this Rule 420-3-26-.09 and the applicable sections of Rule 420-3-26-.03, Agency Notice of Registration and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;

3. Has demonstrated competence to use the particle accelerators, related equipment, and survey instruments which will be employed in their assignment.

(b) Each registrant shall maintain records that document the training of each accelerator operator as required by this rule.

(c) The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

(6) **Operating and Emergency Procedures**. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel. These operating and emergency procedures shall include instructions in at least the following:

(a) The use of particle accelerators such that no person is likely to be exposed to radiation doses in excess of the limits established in Rule 420-3-26-.03 "Standards for Protection Against Radiation";

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to high radiation areas;

(d) Methods and occasions for locking the control panel of the particle accelerators;

(e) Personnel monitoring and the use of personnel monitoring equipment;

(f) Minimizing exposure of persons in the event of an accident;

(g) The procedures for notifying proper persons in the event of an accident; and

(h) Maintenance of records.

(7) **Tests and Surveys**.

(a) All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three (3) months.

(b) A radiation protection survey shall be performed and documented by an authorized medical physicist or a qualified expert as defined in 420-3-26-.01(2)(a)79. when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

(c) Any interlock which has been bypassed or otherwise prevented from operation shall be tested to determine it is functioning properly immediately upon its return to normal use.

(d) The registrant shall retain records of the tests specified in 420-3-26-.09(7)(a), (b), and (c) for inspection by the Agency for two years.

(e) A survey shall be made of each radiation area upon initial entry by personnel into these areas following the operation of the particle accelerator. The registrant shall not be required to make a record of the survey required by this paragraph.

(8) **Therapeutic Particle Accelerator Installations**.

(a) Operation.

1. Administrative Controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the Agency. The registrant or the registrant's agent shall ensure that the requirements of 420-3-26-.09 are met in the operation of the therapeutic radiation machine(s).

2. No individual who receives occupational doses of radiation shall be in the room during irradiation unless he is the patient. No other individual shall be there except when it is clinically necessary.

3. Written safety procedures and rules shall be developed by an authorized medical physicist or a qualified expert and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

4. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

5. The operator shall have at the control panel a copy of the emergency procedures which shall include instructions for:

(i) Turning off the accelerator beam;

(ii) Removing the patient from the treatment room;

(iii) Securing the room against unauthorized entry; and

(iv) Notifying the responsible physicians and/or radiation safety officer.

6. Users of particle accelerators for the treatment of humans shall not be required to have surveys made as required by 420-3-26-.09(7)(e), provided all interlocks and warning lights are operational and functional.

(b) Equipment.

1. Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with these rules shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range one (1) mrem (10 εSv) per hour to 1000 mrem (10 mSv) per hour.

2. Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.

(i) The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two (2) meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters (100 cm^2) at a minimum of sixteen (16) points uniformly distributed in the plane;

(ii) Except for the area defined in Rule 420-3-26-.09(8)(b)2.(i), the absorbed dose due to leakage radiation (excluding neutrons) at one (1) meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters (100 cm^2);

(iii) For equipment manufactured after **(insert effective date of this rule)**, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 (available for purchase at www.web.ansi.org); and

(iv) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in Rule 420-3-26-.09(8)(b)2.(i) through (iii) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the Agency.

3. Stray Radiation in the Useful Beam. For equipment manufactured after the effective date of these rules, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the

useful x-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 (available for purchase at www.web.ansi.org).

4. Leakage Radiation Through Beam Limiting Devices

(i) Photon Radiation. All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 100 cm^2 radiation field, or maximum available field size if less than 100 cm^2;

(ii) Electron Radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(I) A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven (7) centimeters outside the periphery of the useful beam; and

(II) A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two (2) centimeters outside the periphery of the useful beam.

(iii) Measurement of Leakage Radiation.

(I) Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two (2) tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters (10 cm^2);

(II) Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one (1) square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one (1) centimeter of water equivalent build up material.

5. Filters/Wedges

(i) Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on

the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

(ii) If the absorbed dose rate information required by 420-3-26-.09(8)(b)10. relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools;

(iii) For equipment manufactured after December 1, 2014 which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

(I) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

(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 showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and

(IV) An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

6. Beam Quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

(i) The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table I. Linear interpolation shall be used for values not stated.

Table I

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.1
50	0.20

(ii) Compliance 420-3-26-.09(8)(b)6.(i) shall be determined using:

I. a measurement within a phantom with the incident surface of the phantom at the normal treatment distance and perpendicular to the central axis of the beam;

II. the largest field size available which does not exceed 15 by 15 centimeters; and

III. a phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

(iii) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in Table II. Linear interpolation shall be used for values not stated.

Table II

Maximum Photon Energy in MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

(iv) Compliance with 420-3-26-.09(8)(b)6.(iii) shall be determined by measurements made:

I. within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;

II. using a phantom whose size and placement meet the requirements of 420-3-26-.09(8)(b)6.(ii);

III. after removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and

IV. using the largest field size available which does not exceed 15 by 15 centimeters.

(v) The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding scattered neutron radiation, for specified operating conditions.

7. All therapy systems shall be provided with radiation detectors in the radiation head.

(i) Equipment manufactured after December 1, 2014 shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.

(ii) Equipment manufactured on or before December 1, 2014 shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

(iii) The detector and the system into which that detector is incorporated shall meet the following requirements:

I. Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

II. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

III. Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

IV. For equipment manufactured after December 1, 2014, the design of the dose monitoring systems shall assure that:

A. The malfunctioning of one system shall not affect the correct functioning of the second system; and

B. The failure of any system shall terminate irradiation or prevent the initiation of radiation.

V. Each dose monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after December 1, 2014, each display shall:

A. maintain a reading until intentionally reset to zero;

B. have only one scale and no scale multiplying factors;

C. utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an over dosage of radiation, the absorbed dose may be accurately determined; and

D. in the event of power failure, the dose monitoring information required in 420-3-26-.09(8)(b)7.(iii)V displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

8. Beam Symmetry. In equipment manufactured after December 1, 2014 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.

9. 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 pre-selected number of dose monitor units shall be displayed at the treatment control panel until it is reset manually for the next irradiation.

(iii) After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before a subsequent treatment can be initiated.

(iv) For equipment manufactured after December 1, 2014, after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.

10. Air Kerma Rate/Absorbed Dose Rate. For equipment manufactured after December 1, 2014, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in 420-3-26-.09(8)(b)7. may form part of this system.) In addition:

i. The dose monitor unit rate shall be displayed at the treatment control panel;

ii. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

iii. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum

value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

iv. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 420-3-26-.09(8)(b)10.ii. and iii. for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the Agency.

11. Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy.

(i) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

(ii) 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 monitor units, above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

(iii) For equipment manufactured after December 1, 2014, a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent, or 25 dose monitoring units, above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

(iv) For equipment manufactured after December 1, 2014, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

12. 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.

13. Termination Switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

14. Timer.

(i) A timer which has a display shall be provided 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 December 1, 2014, 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 pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

15. 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 (x-rays or electrons) has been made at the treatment control panel.

(ii) An interlock system shall be provided to insure 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.

16. 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 carried out in the treatment room do not agree with the 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, and shall continue to be displayed until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal

energy value selected before subsequent treatment can be initiated;

(iv) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

(iv) For equipment manufactured after December 1, 2014, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 (available for purchase at www.web.ansi.org).

17. Selection of Stationary 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 stationary 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 carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(iv) The mode of operation shall be displayed at the treatment control panel.

(v) For equipment manufactured after December 1, 2014, an interlock system shall be provided to terminate irradiation if:

I. Movement of the gantry occurs during stationary beam therapy; or

II. Movement of the gantry stops during moving beam therapy unless such stoppage is a pre-planned function.

(vi) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement. For equipment manufactured after December 1, 2014:

I. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or 1 cm of linear motion differs by more than 20 percent from the selected value.

II. Where gantry angle terminates the irradiation in moving beam radiation therapy, the dose monitor units shall differ by less than 5 percent from the dose monitor unit value selected.

III. An interlock shall be provided to prevent motion of more than five (5) degrees or one (1) cm beyond the selected limits during moving beam radiation therapy;

IV. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

V. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

(vii) Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by 420-3-26-.09(8)(b)12.

18. Absorbed Dose Rate. For equipment manufactured after December 1, 2014, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. In addition:

(i) The dose monitor unit rate shall be displayed at the treatment control panel.

(ii) If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant.

19. Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

(i) The x-ray target or the virtual source of x-rays; and

(ii) The electron window or the virtual source of electrons if the system has electron beam capabilities.

20. System Checking Facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When pre-selection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

21. Exemption. Users of particle accelerators for the treatment of humans shall not be required to have portable radiation monitoring equipment as required by 420-3-26-.09(4)(d)12., provided all interlocks and warning lights are operational and functional.

(c) Facility.

1. Viewing Systems. 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 may observe the patient from the control panel.

2. Aural Communications. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication shall be used.

3. Exemption. A particle accelerator used only for the treatment of humans shall not be required to have an audible warning device within the treatment room as required by 420-3-26-.09(4)(d)8.

(d) Surveys.

1. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with 420-3-26-.03(17)(b). The radiation protection survey shall be performed by, or under the direction of, an authorized medical physicist as defined in 420-3-26-.08(3) or a qualified expert as defined in 420-3-26-.01(2)(a), and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

(i) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in Rule 420-3-26-.03(6)(a); and

(ii) Radiation levels in unrestricted areas do not exceed the limits specified in Rule 420-3-26-.03(14)(a) and (b).

2. In addition to the requirements of Rule 420-3-26-.09(8)(d)1., a radiation protection survey shall also be performed prior to any subsequent medical use and:

(i) After making any change in the treatment room shielding;

(ii) After making any change in the location of the therapeutic radiation machine within the treatment room;

(iii) After relocating the therapeutic radiation machine; or

(iv) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

3. The survey record shall indicate all instances where the facility, in the opinion of the authorized medical physicist or qualified expert, is in violation of applicable regulations. The survey record shall also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of one (1) week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey.

4. If the results of the surveys required by this rule indicate any radiation levels in excess of the respective limit specified in 420-3-26-.09(8)(d)1., the registrant shall lock the control in the "OFF" position and not use the unit:

(i) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(ii) Until the registrant has received a specific exemption from the Agency.

(e) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by 420-3-26-.09(8)(d) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 420-3-26-.03(14)(a) and (b) of these regulations, before beginning the treatment program the registrant shall:

1. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 420-3-26-.03(14)(a) and (b) of these regulations;

2. Perform the survey required by 420-3-26-.09(8)(d) again; and

3. Include in the report required by 420-3-26-.09(8)(f) the results of the initial survey, a description of the modification made to comply with 420-3-26-.09(8)(e)1. and the results of the second survey; or

4. Request and receive a registration amendment under 420-3-26-.03(14)(c) of these regulations that authorizes radiation levels in unrestricted areas greater than those permitted by 420-3-26-.03(14)(a) and (b) of these regulations.

(f) Reports of External Beam Radiation Therapy Surveys and Measurements. The registrant for any therapeutic radiation machine subject to these rules shall furnish a copy of the records required in 420-3-26-.09(8)(d) and (e) to the Agency within thirty (30) days following completion of the action that initiated the record requirement.

(g) Calibrations.

1. The calibration of systems subject to this rule shall be performed in accordance with the protocol published by the American Association of Physicists in Medicine, or a user submitted protocol having the prior approval of the Agency, before the system is first used for irradiation of patients and thereafter at time intervals which do not exceed one year and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.

2. The calibration shall be performed under the direct supervision of an authorized medical physicist as defined in 420-3-26.08(3), and who is physically present at the facility during the calibration.

3. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous twenty-four (24) months and after any servicing that may have affected system calibration.

(i) For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

(ii) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;

4. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by 420-3-26-.09(8)(g)3.; the correction factors that were determined; the names of the individuals who performed the calibration, intercomparison, or comparison; and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of an authorized medical physicist.

5. Calibrations shall be in sufficient detail that the absorbed dose at a reference point in soft tissue may be calculated to within an uncertainty of 5 percent.

6. The calibration of the teletherapy 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, 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 sizes used,

for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with the therapy beam.

(iii) The uniformity of the radiation field and any dependency upon the direction of the useful beam.

(iv) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

(v) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

7. Records of calibration measurements required by 420-3-26-.09(8)(g)1. and dosimetry system calibrations required by 420-3-26-.09(8)(g)3. shall be maintained for 5 years after completion of the full calibration.

8. A copy of the latest calibration performed pursuant to 420-3-26-.09(8)(g)1 shall be available in the area of the control panel.

(h) Reserved.

(i) Spot Checks. Spot checks shall be performed on all systems subject to 420-3-26-.09 that are utilized to treat humans. Such spot checks shall meet the following requirements:

1. The spot-check procedures shall be in writing, shall have been developed by an authorized medical physicist, shall have been submitted to the Agency, and shall have received Agency approval prior to implementation.

2. If an authorized medical physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by an authorized medical physicist within 35 days. If any significant changes, as defined by the registrantôs spot check procedures, are observed the authorized medical physicist shall be contacted immediately.

3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

4. At intervals not to exceed 1 week, spot checks shall be made of absorbed dose measurements at a typical treatment depth in a phantom. At intervals not to exceed one month, spot checks shall be made of absorbed dose measurements at no less than two depths in a phantom.

5. 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

measurement.

6. The cause for a parameter exceeding a tolerance set by the authorized medical physicist shall be investigated and corrected before the system is used for patient irradiation.

7. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the spot-check procedures, the system shall be recalibrated as required in 420-3-26-.09(8)(g).

8. Records of spot-check measurements and of any corrective actions taken shall be maintained by the registrant for a period of 3 years after completion of the spot-check measurements.

9. Where a spot check involves a radiation measurement, such measurement shall be obtained using a measurement system satisfying the requirements of 420-3-26-.09(8)(g)3. or a measurement system which has been intercompared within the previous year with a system meeting those requirements.

(j) Documentation of Treatments.

1. Treatment Plans:

(i) A written treatment plan must be dated and signed by an authorized user prior to the administration of radiation.

(ii) The written treatment plan must contain the patient or human research subjectôs name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(iii) A written revision to an existing written treatment plan may be made provided that the revision is dated and signed by an authorized user prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

(iv) The registrant shall retain a copy of the written treatment plan.

2. Procedures for Administrations. The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

(i) Prior to the administration of each course of radiation treatments, the patientôs or human research subjectôs identity is verified by more than one method as the individual named in the written treatment plan;

(ii) Each administration is in accordance with the written treatment plan;

(iii) Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written treatment plan by:

(I) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the treatment plan; and

(II) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(iv) Any unintended deviation from the treatment plan is identified, evaluated and appropriate action is taken; and

(v) The registrant retains a copy of the procedures for administrations for the duration of the registration.

4. Each treatment plan shall be reviewed at least once each week or after every five consecutive treatments to ensure that treatments are being delivered according to the plan.

(k) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Agency:

1. Report of acceptance testing;

2. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by this rule, as well as the name(s) of person(s) who performed such activities;

3. Records of maintenance and/or modifications performed on the therapeutic radiation machine after the December 1, 2014, as well as the name(s) of person(s) who performed such services;

4. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

(l) All records required by this rule shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in this rule. All required records shall be retained in an active file from at least the time of generation until the next Agency inspection. Any required record generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Agency authorizes final disposal.

(m) Records and Reports of Misadministration.

1. A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

2. Other than events that result from intervention by a patient or human research subject, when a misadministration, as defined by 420-3-26-.09(2), occurs the registrant shall notify the Agency by telephone no later than the next calendar day after the discovery of a misadministration. The registrant shall also provide notification of the misadministration to the affected patient's referring physician, and the patient or a responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the registrant discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the registrant shall notify them as soon as practicable. The registrant is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the registrant shall not delay medical care, including any necessary remedial care, for the patient because of this. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

3. Within fifteen (15) days after an initial misadministration notification to the Agency, the licensee shall submit a written report to the Agency and to the referring physician. The written report must include:

(i) The Registrant's name;

(ii) The prescribing authorized userôs name;

(ii) The referring physician's name;

(iii) A brief description of the event;

(iv) Why the event occurred;

(iv) The effect on the patient;

(v) Actions, if any, that have been taken, or are planned, to prevent a recurrence;

(vi) Certification that the registrant informed the patient or the patient's responsible relative or guardian, and if not, why not.

4. Each registrant shall retain a record of each misadministration for ten (10) years. The record must contain:

(i) The registrantôs name and the names of all individuals involved in the event including the physician, allied health personnel, the patient, and the patient's referring physician,

(ii) The patient's social security number or identification number if one has been assigned,

(iii) A brief description of the event and why it occurred,

(iv) The effect on the patient,

(v) The actions, (if any), taken, or planned , to prevent recurrence.

(vi) Whether the registrant notified the individual (or the individualôs responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

5. Aside from the notification requirement, nothing in this rule shall affect any rights or duties of registrants, and physicians in relation to each other, patients, or responsible relatives or guardians.

Author: Karl David Walter
Statutory Authority: §§22-14-4, 22-14-7, and 22-14-8 (*Code of Alabama, 1975*).
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APPENDIX A

INSTRUCTION FOR OPERATORS

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