420-3-26-.09

RADIATION SAFETY REQUIREMENTS FOR USERS OF PARTICLE ACCELERATORS

(1) **Scope**. Rule 420-3-26-.03 established 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) "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. For purposes of this definition, "particle accelerator" is an equivalent term.

(b) "Agency" means the Alabama State Board of Health.

(c) "Authorized User" means a practitioner of the healing arts who is identified as an authorized user on an Agency particle accelerator registration that authorizes the medical use of a particle accelerator.

(d) "Beam Scatter Filter" means a filter used in order to scatter a beam of electrons.

(e) "Central Axis of the Beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

(f) "Dose Monitoring System" means a system of devices for the detection, measurement, and display of quantities of radiation.

(g) "Dose Monitor Unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

(h) "Emergency Procedures" 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.

(i) "Existing Equipment" means therapy systems subject to 420-3-26-.08 which were manufactured on or before January 1, 1985.

(j) "Field-Flattening Filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

(k) "Field Size" 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.

(l) "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

(m) "High Radiation Area" 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.

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

(o) "Interruption of Irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(p) "Isocenter" 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.

(q) "Misadministration" means the administration of a Therapeutic Particle Accelerator Dose:

1. Involving the wrong patient or wrong treatment site;
2. When the treatment consists of 3 or fewer fractions and the calculated total absorbed dose administered differs from the total absorbed dose prescribed by more than 10 percent of the total prescribed dose;

3. When the calculated weekly administered dose is 30 percent or more greater than the weekly prescribed dose; or

4. When the calculated total absorbed dose administered differs from the total absorbed dose prescribed by more than 20 percent of the total prescribed dose.

(r) "Moving Beam Therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.

(s) "New Equipment" means systems subject to 420-3-26-.08 which were manufactured after January 1, 1985.

(t) "Normal Treatment Distance" means:

1. for electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer of the applicator.

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

(u) "Operating Procedures" 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.

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

(w) "Personnel Monitoring Equipment" 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.

(x) "Primary Protective Barrier" means a barrier sufficient to attenuate the useful beam to the required degree.

(y) "Protective Barrier" means a barrier of attenuating materials used to reduce radiation exposure.

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

(aa) "Radiation Head" means the structure from which the useful beam emerges.

(bb) "Radiographer" 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.

(cc) "Scattered Radiation" means secondary radiation or radiation that, during passage through matter, has been deviated in direction.

(dd) "Secondary Protective Barrier" means a barrier sufficient to attenuate scattered radiation to the required degree.

(ee) "Shadow Tray" means a device attached to the radiation head to support auxiliary beam limiting material.

(ff) "Stationary Beam Therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

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

(hh) "Teletherapy Physicist" means the individual identified as the qualified teletherapy physicist on an Agency particle accelerator registration or teletherapy license.

(ii) "Visiting Authorized Teletherapy Physicist" means a teletherapy physicist who is not identified on the registration of the registrant being visited.

(jj) "Visiting Authorized User" means an authorized user who is not identified on the registration of the registrant being visited.

(kk) "Virtual Source" means a point from which radiation appears to originate.

GENERAL REQUIREMENTS

(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**. 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. 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 the 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 the correct interval 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. Electrical circuit diagrams of the accelerator and the associated interlock systems shall be kept current and on file 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 subparagraph 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, the access of 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 millirads 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 section 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 his assignment.

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

(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 3 months.

(b) A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the Agency, 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 it's return to normal use.

(d) The registrant shall retain records of the tests specified in subparagraphs (a), (b), and (c) for inspection by the Agency for two years.

(e) A survey shall be made of each radiation area upon the 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 subparagraph.

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

(a) **Operation**.

1. 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.

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

3. 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.

4. 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. **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 system, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 420-3-26-.09(8)(b)1.(i)I for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Agency.

(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 system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in 420-3-26-.09(8)(b)1.(i)I. for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the Agency.

2. **Leakage Radiation Outside the Patient Area (New Equipment Only)**

(i) The absorbed dose in rads (grays) due to leakage radiation except in the area specified in 420-3-26-.09(8)(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 420-3-26-.09(8)(b)1(i)I.

(ii) The registrant shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in 420-3-26-.09(8)(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. **Beam Limiting Devices.** Adjustable or interchangeable beam limiting devices shall be provided. Such devices shall transmit no more than 5 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. 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) If the absorbed dose rate data required by 420-3-26-.09(8)(b)16 relates exclusively to operations with a field-flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.

(iii) For new equipment 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 showing the filter(s) in use; and

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 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	0.10
50	0.20

(ii) Compliance 420-3-26-.09(8)(b)5.(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)5(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)5(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.

6. **Beam Monitors.** All therapy systems 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.

(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 new equipment, 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 element common to both systems which could affect the correct function of both systems shall terminate irradiation.

V. Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, 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) 6.(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.

7. **Beam Symmetry**. In new equipment 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.

8. **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 new equipment, after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.

9. **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 new equipment, 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 new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

10. **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.

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

12. **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 new equipment 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.

13. **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 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.

14. **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.

(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.

15. **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 new equipment, 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.

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.

(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)9.

16. **Absorbed Dose Rate**. For new equipment, 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.

17. **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.

18. **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.

19. **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. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert, as defined in 420-3-26-.01(2)(a)77. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.

3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of any applicable rules.

(e) **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 a teletherapy physicist, who meets the requirements in 420-3-26-.07(74), and is named on the registration, or meets the requirements of 420-3-26-.08(8)(f), or is named on an Agency Particle Accelerator Service Registration, and who is physically present at the facility during the calibration.

3. Calibration radiation measurements required by 420-3-26-.09(8)(e) shall be performed using a dosimetry system:

   (i) having a calibration factor for cobalt-60 gamma rays traceable to a national standard;

   (ii) which has been calibrated within the previous 2 years and after any servicing that may have affected its calibration;

   (iii) which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

   (iv) which has had constancy checks performed on the system as specified by a teletherapy physicist.

4. 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.

5. 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.

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

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

(f) **Visiting Teletherapy Physicist**. A registrant may permit any visiting authorized teletherapy physicist to perform testing and calibration on the particle accelerators on a temporary basis, not to exceed 60 days in a calendar year, if:

1. The visiting teletherapy physicist has the prior written approval of the licensee's management and, if the accelerator is at an institution, the institution's Radiation Safety Committee; and

2. The registrant has a copy of an Agency registration or Agency teletherapy license that identifies the visiting authorized teletherapy physicist by name as an approved teletherapy physicist.

(g) **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 and shall have been developed by a teletherapy physicist, shall have been submitted to the Agency, and shall have received Agency approval prior to implementation.

2. If a teletherapy physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a teletherapy physicist within 35 days. If any significant changes, as defined by the registrant's spot check procedures, are observed the teletherapy 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 teletherapy 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)(e).

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)(e)3 or a measurement system which has been intercompared within the previous year with a system meeting those requirements.

(h) **Documentation of Treatments**.

1. Each registrant shall obtain a written prescription from an authorized user for every human to be treated before using radiation to treat said human. The written prescription shall at a minimum specify the type of radiation and the radiation absorbed dose to be delivered to a specific location over a specified number of treatments.

2. For each individual being treated a treatment plan shall be made by, or under the supervision of, the authorized user or a teletherapy physicist and shall be approved by the authorized user. The treatment plan shall specify the methodology to be utilized to deliver the written prescription.

3. At the completion of each administration, the individual operator delivering the treatment shall at a minimum indicate the absorbed dose delivered and the date of treatment on the treatment plan accompanied by their initials or signature along with a notation of any abnormalities, or unusual occurrences that may have occurred.

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.

5. All modifications or revisions to the treatment plan shall be approved by an authorized user prior to implementation. Approval of which shall be documented by the authorized user's initials or signature.

(i) **Visiting Authorized User** A registrant may permit any visiting authorized user to use the particle accelerator for medical use under the terms of the registration for 60 days each calender year if:

1. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee; and

2. The registrant has a copy of an Agency registration that identifies the visiting authorized user by name as an authorized medical user of a particle accelerator.

(j) **Records and Reports of Misadministration**.

1. When a misadministration, as defined by 420-3-26-.09 (2)(q), occurs the registrant shall notify the Agency, 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 for the patient because of this.

2. Within 15 days after an initial misadministration notification to the Agency, the licensee shall report, in writing, to the Agency and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative or guardian if either was previously notified by the licensee under 420-3-26-.09(8)(j)1. The written report must include:

   (i) The Registrant's name;

   (ii) The referring physician's name;

   (iii) A brief description of the event;

   (iv) The effect on the patient;

   (v) The action taken to prevent a recurrence;

   (vi) Whether the registrant informed the patient or the patient's responsible relative or guardian; and

   (vii) If not, why not.

3. Each registrant shall retain a record of each misadministration for 10 years. The record must contain;

   (i) 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,

(iv) The effect on the patient, and

(v) The action taken, if any, to prevent recurrence.

4. Aside from the notification requirement, nothing in 420-3-26-.09 (8)(j) shall affect any rights or duties of registrants, and physicians in relation to each other, patients, or responsible relatives or guardians.

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Authority: §§22-14-4, 22-14-7, and 22-14-8, Code of Alabama, 1975.

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420-3-26-.09

APPENDIX A

INSTRUCTION FOR OPERATORS

I. Fundamentals of Radiation Safety

A. Characteristics of alpha, beta, gamma, neutrons, and x-radiation

B. Units of radiation dose (mrem) and quantity of radioactivity (curie)

C. Biological effects of radiation

D. Methods of controlling radiation dose

1. Working time
2. Working distance
3. Shielding

II. Radiation Detection Instrumentation to be Used

A. Use of radiation survey instruments

1. Operation
2. Calibration
3. Limitations

B. Survey Techniques

1. Methods of surveys
2. Records which must be made and retained

C. Use of personnel monitoring equipment

III. Operation and Control of Particle Accelerators

IV. The Requirements of State Regulations

V. The Registrant's Written Operating and Emergency Procedures