**Section 360.120 Therapy Systems Operating at 1 MeV or Greater**

In addition to the provisions of Sections 360.10 through 360.30, the requirements of this Section apply to particle accelerator systems operating at energies of 1 MeV or greater. Accelerator systems capable of producing radioactive materials in excess of the exempt quantities specified in 32 Ill. Adm. Code 330.Appendix B shall also be licensed pursuant to the provisions of 32 Ill. Adm. Code 330.

a) Facility Design

1) The registrant shall consult a therapeutic radiological physicist in the design of a particle accelerator installation.

2) Shielding Requirements

A) Each accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with 32 Ill. Adm. Code 340.

B) Facility design information for all accelerators installed after October 15, 1993 shall be submitted to the Agency for review prior to installation. Information submitted to the Agency shall include, but need not be limited to, the following:

i) Name and address of the planned installation;

ii) Name, address and telephone number of the therapeutic radiological physicist who was consulted in the design of the installation;

iii) A scale drawing that includes the location of the accelerator, control panel and doors to the room;

iv) The structural composition and thickness of all walls, doors, partitions, floor and ceiling of the installation;

v) The occupancy of areas adjacent to the installation;

vi) Calculations that demonstrate the adequacy of the amount of shielding specified for each primary and secondary protective barrier; and

vii) Projected weekly dose rates in areas adjacent to the installation.

3) Interlock. An interlock shall be installed on each door of the therapy room. The interlock shall be wired into the electrical circuit in such a manner that when the door is opened for any reason, the generation of radiation beams will automatically be terminated and irradiation can be resumed only by manually resetting the controls on the control panel after the door is closed.

4) Warning lights that indicate when the beam is on shall be provided in a readily observable position near the outside of all access doors to the therapy room.

5) Viewing System. Windows, mirrors, closed-circuit television or an equivalent system shall be provided to permit continuous visual observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.

AGENCY NOTE: When the primary viewing system is electronic, a back-up system should be available for use in the event of failure of the primary system in order to ensure compliance with the requirements of subsection (g)(1)(H).

6) The facility design shall permit two-way aural communications between the patient and the operator at the control panel.

7) Signs required by 32 Ill. Adm. Code 340.920 shall be posted in the facility.

8) The control panel shall be outside the therapy room.

9) The facility design shall include emergency off buttons, at locations that allow shutting off the machine from inside the therapy room and at the control panel.

10) The doors to the therapy room shall be designed to allow opening from the inside at all times and shall be capable of being opened manually.

b) Equipment Requirements

1) Leakage radiation to the patient area shall be measured for each accelerator. Measurements shall be repeated following maintenance or service performed on the accelerator, as determined by a therapeutic radiological physicist.

A) For operating conditions producing maximum leakage radiation, the absorbed dose due to leakage radiation, excluding 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 of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Radiation measurements shall be averaged over an area up to but not exceeding 100 square centimeters.

B) Records of the most recent radiation leakage measurements and the machine parameters used during the survey shall be maintained at the facility for inspection by the Agency.

2) Beam-Limiting Devices. Adjustable or interchangeable beam-limiting devices shall transmit no more than two percent of the useful beam at the normal treatment distance for the portion of the useful beam that is to be attenuated by the beam-limiting device. The neutron component of the useful beam shall not be subject to this requirement. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

3) Source-Skin Distance (SSD) Indication

A) Means shall be provided to indicate the SSD.

B) The SSD shall be indicated in centimeters and/or inches and the measured SSD shall correspond to the indicated value to within 0.5 percent.

4) Filters

A) Each filter that 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 and maximum design field size shall appear on the wedge or wedge tray.

B) If the machine calibration measurements required by subsection (d) relate exclusively to operation with an x-ray field flattening filter or electron beam scattering filter in place, such filters shall be removable from the machine only by the use of tools.

C) Equipment utilizing a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters shall meet the following requirements:

i) The equipment shall have an interlock that prevents irradiation if any filter selection operation carried out in the therapy room is not consistent with the selection of filter, beam type or beam energy at the control panel; and

ii) The equipment shall have an interlock system that prevents irradiation if any selected filter is not in the correct position.

5) Beam Monitoring System. All accelerator systems shall be provided with a beam monitoring system in the radiation head capable of monitoring and terminating irradiation.

A) Each beam monitoring system shall have a display at the treatment control panel which shall register accumulated monitor units.

B) The beam monitoring system shall terminate irradiation when the preselected number of monitor units has been detected by the system.

C) Accelerator systems manufactured after October 15, 1993 shall be equipped with a primary and a secondary beam monitoring system. Each beam monitoring system shall be independently capable of monitoring and terminating irradiation.

D) For units with a secondary beam monitoring system, the primary beam monitoring system shall terminate irradiation when the preselected number of monitor units has been detected. The secondary beam monitoring system shall terminate irradiation if the primary system fails.

E) An interlock device shall prevent irradiation if any beam monitoring system is inoperable.

F) In the event of power failure, the display information required in subsection (b)(5)(A), shall be retrievable in at least one system for 20 minutes.

6) Beam Symmetry. For equipment equipped with beam bending magnets, the symmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam-limiting device. The equipment shall provide means of terminating irradiation automatically if the difference in dose rate between one region and another region exceeds criteria specified by the manufacturer.

7) Control Panel

A) Selection and Display of Monitor Units

i) Irradiation shall not be possible until a selection of a number of monitor units has been made at the control panel.

ii) The selected number of monitor units shall be displayed at the control panel until reset.

iii) After completion of irradiation, it shall be necessary to reset the accumulated beam monitor units before treatment can be restarted.

B) Termination of Irradiation. It shall be possible to terminate irradiation and equipment movements at any time from the operator's position at the control panel.

C) Selection of Radiation Type. Equipment capable of both photon and electron therapy shall meet the following requirements:

i) Irradiation shall not be possible until the radiation type has been selected and displayed at the control panel.

ii) An interlock shall be provided to ensure that the machine will emit only the radiation type that has been selected.

iii) An interlock shall be provided to prevent irradiation with x-rays, except to obtain port films, when electron applicators are installed.

iv) An interlock shall be provided to prevent irradiation with electrons if accessories specific for x-ray therapy are installed.

D) Selection of Radiation Energy. Equipment capable of producing 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 control panel.

ii) An interlock shall be provided to ensure that the machine will emit only the nominal energy of radiation that has been selected.

iii) The nominal value of the energy selected shall be displayed at the treatment control panel.

E) Selection of Stationary or Moving Beam Therapy. Equipment capable of both stationary and moving beam therapy shall meet the following requirements:

i) Irradiation shall not be possible unless either stationary therapy or moving beam therapy has been selected at the control panel. The selection of stationary therapy may be performed as a default selection if moving beam therapy is not selected.

ii) An interlock shall be provided to ensure that the machine will operate only in the mode that has been selected.

iii) An interlock shall be provided to terminate irradiation if the gantry fails to move properly during moving beam therapy.

iv) Means shall be provided to prevent movement of the gantry during stationary therapy.

v) The mode of operation shall be displayed at the control panel.

F) Timers. A timer shall be provided with a display at the treatment control panel, as a back-up device to the beam monitoring system.

i) The timer shall permit presetting and determination of exposure times.

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.

iii) The timer shall terminate irradiation when a preselected time has elapsed if the beam monitoring system has not previously terminated irradiation. If set at zero, the timer shall not permit irradiation.

G) Security. The control panel shall be capable of being locked to prevent unauthorized use.

c) Radiation Protection Survey. A radiation protection survey shall be performed by a therapeutic radiological physicist on each accelerator. The registrant shall maintain at the facility a copy of the most recent radiation protection survey report for review by the Agency. Radiation protection surveys shall meet the following additional requirements:

1) For each accelerator installed after October 15, 1993, a radiation protection survey shall be performed by a physicist before the system is first used for irradiation of a patient. The physicist who performs the radiation protection survey shall be a person who did not consult in the design of the accelerator installation (see subsection (a)) and is not employed by or within any corporation or partnership with the person who consulted in the design of the installation.

2) A radiation protection survey shall be performed by a physicist after any change in the accelerator or facility that might produce a radiation hazard. Such survey shall be performed before the system is used to treat patients.

3) The survey report shall include, but need not be limited to, the following:

A) A diagram of the facility which details building structures and the position of the control panel, accelerator and associated equipment;

B) A description of the accelerator system including the manufacturer, model number, beam type and beam energy range;

C) A description of the instrumentation used to determine radiation measurements, including the date and source of the most recent calibration for each instrument used;

D) Conditions under which radiation measurements were taken;

E) Survey data including:

i) Projected weekly dose equivalent in areas adjacent to the therapy room; and

ii) A description of workload, use and occupancy factors employed in determining the projected weekly dose equivalent.

4) The registrant shall retain a copy of the radiation protection survey report and a copy of the report shall be provided to the Agency within 30 days after completion of the survey.

5) Any deficiencies detected during the radiation protection survey that would constitute or result in a violation of 32 Ill. Adm. Code 340 shall be corrected prior to using the machine for treatment of patients.

6) The facility shall be operated in compliance with any limitations indicated by the therapeutic radiological physicist as a result of the radiation protection survey.

d) Machine Calibration. Calibration measurements shall be performed on each accelerator system by a therapeutic radiological physicist before the therapy system is first used for irradiation of a patient. Subsequent calibrations shall be performed at intervals not exceeding 1 year.

1) Calibration measurements shall include, but need not be limited to, the following determinations:

A) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, variation in the axes of rotation for the table, gantry and jaw system and the beam flatness and symmetry at the specified depth;

B) The absorbed dose rate at various depths in water for the range of field sizes used, for each beam type and energy;

C) The uniformity of the radiation field and any dependency upon the direction of the beam;

D) 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; and

E) Verification of transmission factors for all accessories such as wedges, shadow trays and compensators, as applicable.

2) Calibration radiation measurements shall be performed using a dosimetry system that has been calibrated by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM), and meets the requirements of either subsection (d)(2)(A) or (B):

A) The calibration shall have been performed within the previous 2 years and after any servicing that may have affected calibration of the dosimetry system; or

B) The dosimetry system shall have been calibrated within the previous 4 years and shall have been:

i) Compared at annual intervals following the calibration to a dosimetry system with calibration obtained within the previous 2 years from a calibration laboratory accredited by the AAPM, and the results of the comparison indicate the calibration factor has not changed by more than two percent; or

ii) Subjected to a testing protocol that has been established by a therapeutic radiological physicist and that provides for checks of dosimetry constancy and provides for corrective action when results deviate more than two percent from the expected values.

AGENCY NOTE: Redundancy is a basic tenet of radiation dosimetry, therefore the therapeutic radiological physicist should establish a program of inter-comparison and constancy testing of calibrated dosimetry instruments to assure, as much as possible, the accuracy, reliability and reproducibility of the measurements performed with those instruments.

3) Calibration of the radiation output of the accelerator shall be performed in accordance with:

A) The protocol of Task Group 21, Radiation Therapy Committee, American Association of Physicists in Medicine (AAPM), entitled "A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams" published in Medical Physics, Volume 10, pages 741-771 (1983), exclusive of subsequent amendments or editions; or

B) The protocol of the Scientific Committee on Radiation Dosimetry of the AAPM, entitled "Protocol for the Dosimetry of X and Gamma Ray Beams with Maximum Energies Between 0.6 and 50 MeV", published in Physics, Medicine, and Biology, Volume 16, pages 379-396 (1971), exclusive of subsequent amendments or editions; or

C) Other machine calibration protocols provided that the registrant has submitted the protocols to the Agency and the protocols cover the same topics as those contained in subsections (d)(3)(A) and (B).

AGENCY NOTE: Copies of the two protocols referenced in subsections (d)(3)(A) and (B) are available for public inspection at the Illinois Emergency Management Agency, 1035 Outer Park Drive, Springfield, Illinois. The protocols may also be obtained directly from the AAPM, One Physics Ellipse, College Park MD 20740-3846.

4) The radiation output of each therapy system shall be independently verified at intervals not to exceed 2 years. Independent verification shall consist of:

A) Verification of the machine output by a therapeutic radiological physicist who is not employed at the facility and does not perform the annual calibration; or

B) Alternate methods of verification of machine output, such as the use of mailed dosimetry devices, that use devices and procedures approved by the AAPM.

5) Machine calibration records shall include identification of the accelerator calibrated, the results of the tests specified in subsection (d)(1) and shall be signed and dated by the therapeutic radiological physicist who performed the calibration.

6) The registrant shall maintain at the facility, for a period of 5 years, records of machine calibrations, instrument calibrations and independent verifications of machine output for inspection by the Agency.

e) Quality Assurance Checks. A quality assurance (QA) check shall be performed by a therapeutic radiological physicist on each therapy system each calendar month. The interval between QA checks shall not exceed 45 days. QA checks shall also be performed after any change which could affect the radiation output, spatial distribution or other characteristics of the therapy beam, as determined by the physicist. Quality assurance checks shall also meet the following requirements:

1) Quality assurance checks shall include determination of:

A) The radiation output for a set of operating conditions specified by a therapeutic radiological physicist; and

B) The coincidence of the radiation field and the field indicated by the localizing device.

2) Radiation measurements shall be obtained using a dosimetry system that:

A) Meets the requirements of subsection (d)(2); or

B) Has been directly compared by a therapeutic radiological physicist within the previous year with a dosimetry system which meets the requirements of subsection (d)(2).

3) The therapeutic radiological physicist shall establish criteria for quality assurance check measurements and shall determine corrective actions to be implemented if the criteria are exceeded.

4) The registrant shall retain a record of quality assurance check measurements for inspection by the Agency for a period of 5 years. The record shall include the date of the quality assurance check, identification of the accelerator, results of the quality assurance check measurements and the signature of the individual who performed the quality assurance check.

f) Quality Control. A comprehensive quality control program shall be implemented as specified by a therapeutic radiological physicist and shall meet the following requirements:

1) The program shall be designed to test the operation and performance of the accelerator in order to maintain radiation safety and clinical reliability. The program shall include as a minimum the items listed in Section 360.Appendix E.

2) The physicist shall specify the tolerance and frequency of performance for each item of the quality control program.

3) The physicist shall specify what actions are to be taken for any item exceeding the specified tolerance.

4) The physicist shall review, sign and date the results of the quality control program each calendar month.

AGENCY NOTE: The elements of a comprehensive quality control program are described in Report No. 13 published by the AAPM, entitled "Physical Aspects of Quality Assurance in Radiation Therapy" (1984). A copy of this report is available for public inspection at the Illinois Emergency Management Agency, 1035 Outer Park Drive, Springfield, Illinois. Report No. 13 may also be obtained directly from the AAPM, One Physics Ellipse, College Park MD 20740-3846.

g) Operating Procedures. The registrant shall have a therapeutic radiological physicist establish written operating and emergency procedures and shall ensure that the procedures are implemented before the accelerator is used for treatment of patients. Operators of accelerators shall receive training in the application of the procedures before using the accelerator to irradiate patients. A copy of the current operating and emergency procedures shall be maintained at the treatment control panel for use and review.

1) Operating procedures to be implemented shall include instructions that:

A) The accelerator is used in such a manner that patients, workers and the general public are protected from radiation hazards and the provisions of 32 Ill. Adm. Code 340 are met;

B) No accelerator shall be left unattended unless it is secured against unauthorized use;

C) The safety interlock system shall not be used to turn off the beam except in an emergency;

D) The safety interlocks and warning systems required in subsections (a)(3), (a)(4) and (a)(9) shall be tested for proper operation at monthly intervals;

E) Mechanical supporting or restraining devices shall be used when a patient must be held in position for radiation therapy;

F) No individual other than the patient shall be in the therapy room during irradiation;

G) Start-up procedures for the accelerator, specified by the therapeutic radiological physicist, shall be performed daily prior to treatment of patients; and

H) The accelerator shall not be used for treatment of patients unless the operator can maintain visual observation of the patient and audible communication with the patient.

2) Emergency procedures shall include instructions for alternate methods for termination of irradiation and machine movements.

AGENCY NOTE: The operating and emergency procedures should contain as a minimum the machine manufacturer's operations manual for the accelerator.

3) Operating and emergency procedures shall include instructions for contacting the therapeutic radiological physicist when operational problems or emergencies occur and the actions that are to be taken until the physicist can be contacted.

h) Machine Maintenance. The therapeutic radiological physicist shall establish accelerator maintenance procedures that meet the following requirements:

1) Whenever service or maintenance is performed on the accelerator, a therapeutic radiological physicist shall be notified of such service or maintenance.

2) Following completion of service or maintenance involving radiation beam generation, beam steering or monitoring of the beam, but before the accelerator is again used for treatment of patients, the therapeutic radiological physicist shall review the service or maintenance report and shall determine whether a calibration or quality assurance check is necessary to verify the characteristics of the beams. If the therapeutic radiological physicist determines that a calibration or quality assurance check is necessary, the calibration or quality assurance check shall be performed before the accelerator is again used for treatment of patients.

3) The therapeutic radiological physicist shall establish the frequency of routine maintenance and ensure that records of all service and maintenance performed on the machine are maintained at the facility.

4) The therapeutic radiological physicist shall sign and date records of all service and maintenance performed on the machine.

5) The therapeutic radiological physicist shall specify the qualifications of maintenance personnel and prohibit non-qualified personnel from repairing the machine or adjusting parameters on the machine.

6) Circuit diagrams of the accelerator and interlock systems shall be maintained at the facility and kept current.

i) Quality Management Program. Each registrant shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the physician. The quality management program shall address, as a minimum, the following specific objectives:

1) Written Directives. A written directive must be dated and signed by a physician prior to the administration of radiation.

A) A written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

B) A written revision to an existing written directive may be made provided that the revision is dated and signed by a physician prior to the administration of the external beam dose, or the next fractional dose.

C) An oral revision to an existing written directive is acceptable provided that:

i) a delay in providing a written revision would jeopardize the patient's health; and

ii) the oral revision is documented as soon as possible in writing in the patient's record; and

iii) a revised written directive is signed by a physician within 48 hours after the oral revision.

D) The registrant shall retain a copy of each written directive for 3 years.

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

A) Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

B) Each administration is in accordance with the written directive;

C) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;

D) Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken; and

E) The registrant retains a copy of the procedures for administrations for three years.

3) Reports and Notifications of Medical Events

A) A registrant shall report any event 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.

B) Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which:

i) The administration of a therapeutic radiation machine therapy dose involves the wrong patient, wrong treatment modality, or wrong treatment site; or

ii) The calculated weekly administered dose differs from the weekly prescribed dose by more than (30%); or

iii) The calculated total administered dose differs from the total prescribed dose by more than (20%) of the total prescribed dose;

C) The registrant shall notify the Agency by telephone no later than the next calendar day after the discovery of a medical event.

D) The registrant shall submit a written report to the Agency within 15 days after the discovery of a medical event. The written report must include:

i) The registrant's name;

ii) The name of the prescribing physician;

iii) A brief description of the event;

iv) Why the event occurred;

v) The effect, if any, on the individuals who received the administration;

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

vii) Certification that the registrant notified the individual (or the individual's responsible relative or guardian) and if not, why not.

E) The report shall not contain the individual's name or any other information that could lead to the identification of the individual.

F) The registrant shall provide notification of the event to the referring physician and shall notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care required as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection (i)(3)(F), the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. 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 the written description if requested.

G) Aside from the notification requirement, nothing in this Section affects any rights or duties of registrants and physicians in relation to each other, to an individual affected by the medical event, or to that individual's responsible relatives or guardians.

H) The registrant shall retain a record of a medical event in accordance with subsection (i)(4). A copy of the record required shall be provided to the referring physician, if other than the registrant, within 15 days after discovery of the medical event.

I) The registrant shall annotate a copy of the report provided to the Agency with:

i) The name of the individual who is the subject of the event;

ii) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

iii) A copy of the annotated report to the referring physician, if other than the registrant, no later than 15 days after the discovery of the event.

4) Records of Medical Events. A registrant shall retain a record of medical events for 3 years. The record must contain the following:

A) The registrant's name and the names of the individuals involved;

B) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the medical event;

C) A brief description of the event; why it occurred; the effect, if any, on the individual;

D) The actions, if any, taken or planned to prevent recurrence; and

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

(Source: Amended at 38 Ill. Reg. 12031, effective May 29, 2014)