TECHNICAL WHITE PAPER:
GUIDANCE FOR STATE PROGRAMS THAT REGULATE PROTON THERAPY

H-42 TASK FORCE ON PROTON THERAPY

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H-42 TASK FORCE ON PROTON THERAPY

The CRCPD H-42 Task Force was assigned to survey states to determine what is currently being regulated and inspected with regards to proton therapy. Secondly, the Task Force was asked to write a white paper that x-ray inspectors may use as guidance during the routine inspection of proton therapy facilities. The suggested protocol(s) should address any specific paperwork that should be reviewed including but not limited to quality assurance protocols and documentation, physicist credentials, operator training, and operating and emergency procedures. Consideration may also be given to specific measurement protocols that may be undertaken as part of the inspection process by the state inspector. The protocol may include additional information useful for inspection purposes but not directly related to the inspection process.

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EXECUTIVE SUMMARY

CRCPD H-42 Task Force was assigned to survey states to determine what is currently being regulated and inspected with regards to proton therapy. Secondly, the Task Force was asked to write a white paper that x-ray inspectors may use as guidance during the routine inspection of proton therapy facilities.

Task Force H-42 developed a proton beam therapy survey questionnaire to assess the current state of regulations in the U.S. It was mailed to all state and the large city programs; 27 responses were received. A guide for inspections was created addressing elements of the inspection process and specifics of questions to be reviewed.

The report of Task Force H-42 also includes a brief history of proton beam therapy and the basic physics of proton beam interaction with matter. Common clinical proton accelerators are described.

INTRODUCTION

The technology used in healthcare, in general, and radiation medicine has made great advances in the last 70 years and the pace is increasing. Advances in technology have contributed to the wider use of proton beam therapy. The U.S. Nuclear Regulatory Commission (NRC) regulates the use of radioactive materials in the diagnosis and treatment of diseases, either directly or through Agreement State radiation control programs. Accelerator based treatments are regulated by individual state agencies that have to develop/revise regulations in the fast-changing field of radiation oncology. CRCPD plays a vital role in developing guidance documents for State radiation control programs, in order to ensure patient, worker and public safety and quality of care. H-42 Task Force is charged with developing a guidance document for Proton Beam Therapy, for use by inspectors from state radiation control programs.

This document gives a brief history of proton beam therapy and the basic physics of proton beam interaction in the matter. Common clinical proton accelerators are described. H-42 Task Force has developed a checklist for inspection. This list covers machines, ancillary equipment used for treatment planning such as CT, MRI units and their treatment planning system. Also included are sample checklists for patient medical records review and radiation shielding evaluation and survey. The equipment checklist has been kept generic because each facility may have a unique combination of an accelerator, beam transport, and beam delivery systems. It is recommended that the inspector refer to the initial application submitted by the facility to have a working floor plan for use during the first inspection. These diagrams may be updated during that visit and can be used as a reference for subsequent inspections.

HISTORY OF PROTON BEAM THERAPY

In a 1946 paper, Robert Wilson made the first suggestion that energetic protons could be an effective treatment method. At the Berkeley Radiation Laboratory in 1954 and at Uppsala in Sweden in 1957, early proton treatments were performed with accelerators built for physics research. In 1961, a collaboration between the Harvard Cyclotron Laboratory (HCL) and the Massachusetts General Hospital (MGH) started a proton therapy program. Over the next 41 years, this program refined and expanded these techniques, treating thousands of patients until 2002 when the cyclotron was shut down. In 1989, the world's first hospital-based proton therapy program using a low-energy cyclotron for ocular tumors opened at the Clatterbridge Centre for Oncology in the United Kingdom. In 1990, the Loma Linda University Medical Center (LLUMC) in Loma Linda, California started a proton beam therapy program. Later, the Northeast Proton Therapy Center (NPTC) came online at the MGH and the HCL treatment program was transferred to it during 2001 and 2002. At this time (2019), there are more than 30 centers offering proton beam therapy in the United States and many more in operation and under construction or being planned worldwide. For a listing, see Particle Therapy Co-Operative Group https://www.ptcog.ch/index.php/facilities-in-operation

USE OF PROTON BEAMS IN RADIATION THERAPY

DEPTH DOSES OF PHOTON AND PROTON BEAMS

The main advantage of protons for therapy arises from the fact that their interaction with matter and therefore, energy deposition, is markedly different from photons used in conventional radiation therapy. Photons undergo a short buildup region, the width of which is energy dependent, and then show an exponentially decreasing energy deposition with increasing depth in tissue. In contrast, protons show an increasing energy deposition with depth, leading to a maximum (the Bragg peak) near the end of the range of the proton beam, a 1904 discovery by William Henry Bragg. Beyond the Bragg peak, the dose fall off is steep. See Figure 1.

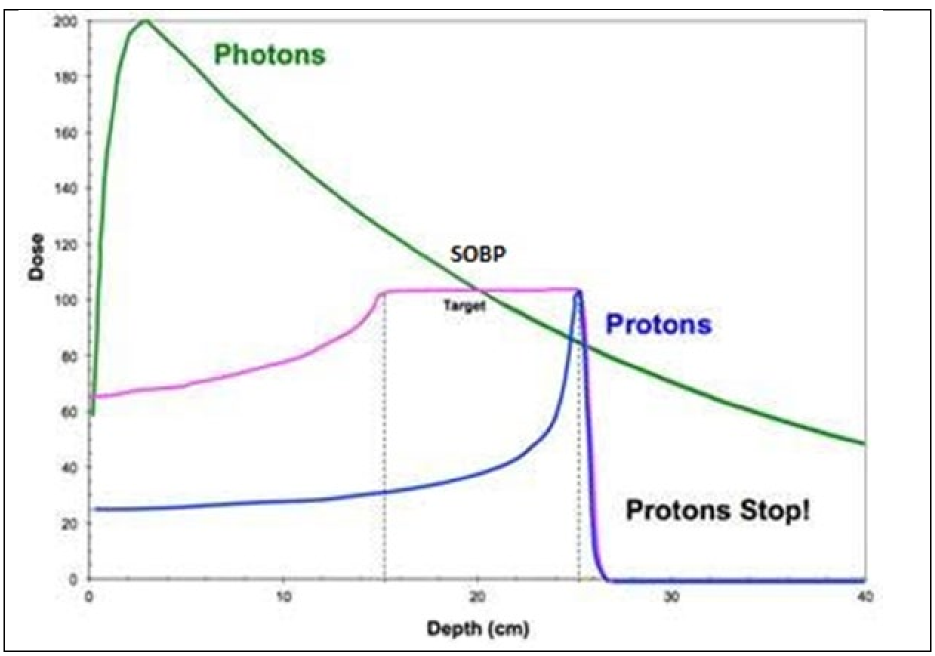

Figure 1. Schematic depth dose curves of photon and proton beams.

Open source graphic.

This physical characteristic of protons provides an advantage of proton treatment over conventional radiation because the region of maximum energy deposition can be positioned within the desired treatment volume for each beam direction, by a careful choice of the beam energy. A conformal high dose region can be created by a Spread Out Bragg Peak (SOBP), as shown by the modified 250 MeV proton beam in Figure 1, making it possible to cover the intended treatment volume with a high degree of accuracy, while delivering lower doses to healthy tissue than conventional photon therapy (integral non-target dose).

Protons are used to treat conditions in two broad categories.

Protons are used to treat diseases/sites that respond well to higher doses from protons, resulting in higher probability of tumor control, than with conventional radiation therapy. Examples are uveal melanoma (ocular tumors), skull base and paraspinal tumors (chondrosarcoma and chordoma), and unresectable sarcomas.

The second category is those treatment sites where proton therapy's lower integral dose to healthy or non-target volumes provides distinct advantages, such as for pediatric tumors. Here, the tumor dose is the same as in conventional therapy, with the same probability of curing the disease. However, the reduction of the integral dose to normal tissue results in reducing unwanted latent effects and can reduce the probability of occurrence of secondary cancers in nearby healthy tissues.

TECHNOLOGY OF PROTON BEAM RADIATION THERAPY

PROTON ACCELERATORS

Proton beam accelerators used for therapy require a high grade of reliability, low maintenance, and ease of operation, in addition to being able to produce dose rates of at least 1 Gy/minute to a liter of water and field sizes as large as 30 cm X 30 cm or larger. Machine downtimes should be minimized because it will inconvenience the patient and deviation from established fractionation schedules may compromise treatment outcome. Low-energy proton beams can only be used for superficial tumors. For example, a 70 MeV proton beam is suitable for treating ocular tumors. To treat other tumors in the human body, with a depth as much as 32 cm, the accelerator has to be able to deliver a beam with energies up to 250 MeV.

Synchrotron

A synchrotron is a circular accelerator ring. The protons are accelerated to about 2-7 MeV, using one or two linear accelerators, before they enter the synchrotron. Electromagnetic resonant cavity around the ring accelerate the particles during each circulation. Since particles move always on the same radius, as they gain energy, the strength of the magnetic field used to steer them must be changed with each turn. This synchronization of field strength and energy gave rise to the name synchrotron to this type of accelerator. This technique allows the production of proton beams with a variety of energies from as low as 70 MeV to as high as 250 MeV.

Cyclotron

A cyclotron consists of dipole magnets designed to produce a region of a uniform magnetic field. An electric field is produced across the gap by an oscillating voltage. Charged particles injected into the magnetic field region move on a semicircular path until they reach the gap where they are accelerated. With increased energy, the particles follow a semi-circular path with a larger radius and when they reach the gap again, the direction of the field has reversed and the particles are accelerated again, traversing a semicircular path with a larger radius, allowing the extraction of a single high energy proton beam (the highest required). Medical cyclotrons used for proton therapy accelerate protons to about 230-250 MeV. To account for the increasing mass of the particle as its speed approaches that of light, the classic cyclotron has been modified. Cyclotrons can be either isochronous or synchrocyclotrons.

In an isochronous cyclotron, the orbital period is the same for all particles regardless of their energy or radius. However, the magnetic field strength increases with increasing radius along with azimuthal variations in the field strength, focusing the particles captured in their spiral trajectory. An isochronous cyclotron is therefore also called azimuthal varying field (AVF) cyclotron. Thus, the radiofrequency range (RF) power can operate at a single frequency. Isochronous cyclotrons provide a continuous beam. Since the acceleration of particles in a cyclotron takes usually only tenths of a millisecond, the beam can be turned on and off quickly, through an external injection system. This feature allows the beam current to be modified during delivery with short response times. Therefore cyclotron based proton therapy systems require energy selection systems. Energy selection systems produce large neutron fluxes, a fact which strongly influences the shielding design.

A synchrocyclotron is a cyclotron in which the frequency of the driving RF electric field is varied over time (continually decreased so as to maintain cyclotron resonance for relativistic velocities). Synchrocyclotrons can be made compact using high magnetic fields. However, the machine produces relatively low intensity beams. Superconducting cyclotrons have a smaller footprint, are a lot lighter and consume less energy.

Cyclotron vs. Synchrotron

Cyclotron intensities are limited by the ion source injection rate to about 800 nanoAmperes at present (2019). Higher currents are not used for conventional proton therapy because the feedback time for machine control would be inadequate. Another disadvantage of cyclotrons is the inability to change the energy of the extracted particles directly. Energy degradation by material in the beam path leads to an increase in energy spread and beam emittance and reduces the efficiency of beam delivery, with double scattering systems providing only about 20% efficiency. The secondary radiation produced by the energy selection systems requires additional shielding. In this respect, a synchrotron is a more flexible solution. A synchrotron allows beam extraction for any energy. Synchrotrons are, however, much larger than cyclotrons.

BEAM TRANSPORT SYSTEMS

The energy of the proton beam is varied during treatment to produce a Spread Out Bragg Peak (SOBP), with the different energies weighted so as to deliver uniform dose to the target volume. By varying (modulating) the number of peaks, the extent of the uniform dose region can be varied to cover the volume of the tumor and margin. Beam energy is varied by energy stacking (energy change upstream of the nozzle) or using a range modulator wheel, a ridge filter or a range shifter.

The beam has to be transported from the accelerator to the treatment room(s) using magnets for bending, steering, and focusing. Detectors monitoring the beam are located in the beamline to control certain tolerances for beam delivery. Each proton treatment room has a beam delivery system ending in a nozzle. The nozzle may have accessories to shape and spread the beam for treatment and also monitor the beam with ionization chambers and other beam monitoring equipment.

BEAM DELIVERY SYSTEMS

Fixed Beams vs. Gantry

In fixed beam treatment rooms, the beam is directed with magnets to a nozzle which is fixed in space. Then, the patient is rotated and translated with a robotic system to enable beam incidence from various angles to cover the target for the desired dose distribution. The use of robotic couches allows one to broaden the variety of disease sites that can be treated on fixed horizontal beamlines. Such conformal radiation therapy requiring multiple beams coming in from different directions can also be achieved through a gantry mounted treatment head. The beam must be deflected by magnetic fields in the gantry. Gantries are usually large structures because (i) protons with therapeutic energies can only be bent with large radii, and (ii) beam monitoring and beam shaping devices must be positioned inside the treatment head affecting the size of the nozzle. Treatment nozzles consist of ionization chambers to monitor beam position, beam current, the beam size and uniformity and scatterers/absorbers for scattered beams. Sometimes, the nozzle also has a snout that permits mounting and positioning of the field-specific aperture and compensator along the beam axis for scattered beams. Fixed beam rooms are smaller than gantry rooms. Patients may be treated in a seated or nearly seated position, or prone or supine, depending on the disease site and technology in use at the facility. Currently, the majority of treatments (besides ocular) are delivered with gantries. The installation can be designed with either a single treatment room or multiple treatment rooms, usually with one room receiving the proton beam at a time.

Scattering Systems vs. Scanning Systems

Scattered Beam

The beam has to be uniform across the field sizes that can range from as small as 1 cm to as large as 30 cm or more. For small fields, a single scattering foil can be used to broaden the beam. For larger field sizes, a double-scattering system is used to produce a uniform, flat lateral dose profile. The double scattering system may contain a first scatterer (set of foils), placed upstream near the nozzle entrance, and a second one placed further downstream.

Pristine Bragg peaks are too narrow to cover most treatment depths and volumes. The incident proton beam needs to be spread out in the direction of beam incidence. This SOBP is produced by the use of penetrating absorbers of variable thickness, e.g. via a range modulator or a ridge filter. A modulator wheel combines variable thickness absorbers in circular rotating tracks that result in a temporal variation of the beam energy. Ridge filters are comb-like devices with variable vertical thicknesses. Using these devices, a composite SOBP is designed until the desired modulation is achieved.

Treatment fields are shaped to match the individual patient's target using custom milled apertures made of brass, analogous to the shielding blocks used in photon beam therapy prior to the advent of multi-leaf collimators (MLC). The distal part of the dose distribution is shaped according to the desired dose distribution, using custom made compensators made of plastic to reduce the range of the protons. Both the aperture and the compensator are mounted on a retractable snout on the treatment head.

A hybrid technique called wobbling, or uniform scanning, involves a relatively broad beam (about 5 cm diameter) that is magnetically scanned across the target volume. Collimators are still needed in this case because of a large penumbra. Wobbling can produce larger field sizes than is possible with passive scattering.

Scanned Beam

Recent proton beam technology uses the scanned beam technique. Since protons can be deflected magnetically, an alternative to the use of a broad beam is to generate a narrow mono-energetic pencil beam and to spot scan it magnetically perpendicular to the direction of the beam (x, y) across the target volume. The depth scan (z) is acquired by means of energy variation. Scanning does not require either scatterers or the modulation wheels in the nozzle, nor the patient specific devices such as a collimator or a compensator. Several proton scanning techniques are available.

With scanning, it is possible to deliver a uniform high dose to arbitrarily shaped volumes with a single beam. Another advantage of the scanning approach is that, in the absence of scatterers to produce an SOBP, there is less nuclear interaction outside of the patient and therefore less neutron production. The flexibility offered by the scanning technique can be fully utilized in intensity modulated proton therapy (IMPT), with intentionally non-uniform dose distributions from each treatment field delivered in a given direction, and their superposition can yield desired (generally uniform) dose in the target volume. The scanning approach can also be more sensitive to organ motion than passive scattering.

TREATMENT PLANNING

Several algorithms have been developed to calculate the dose distribution in proton beam therapy and commercial treatment planning systems are available. Monte Carlo dose calculations, currently considered the most accurate for proton beam therapy, use physical treatment machine data to model proton interaction in the treatment modifying devices and patient.   As with photons, proton treatments use multiple portals to reduce the overall skin dose to patients. Multiple beams also help spread out the entrance dose and can account for the end of range uncertainties. Since proton beams have a sharp distal fall-off, with dose levels dropping from 90% to 10% in less than a cm, it is important to understand and limit the uncertainties in determining the range. These uncertainties must be incorporated in the treatment planning margins around the target volume and organs at risk, in addition to accounting for uncertainties caused by beam delivery, patient set up and immobilization, tissue heterogeneities, and intra- and inter- fractional changes. Margins of a few mm to more than a cm beyond the tumor may be included in the planning target volume. Selection of irradiation directions and target margin expansion, design of beam-modifying devices (e.g., range compensators), or, for pencil beam based delivery, robust optimization methods are some of the ways uncertainties can be addressed in proton therapy planning. Although the SOBP leads to some loss of skin sparing compared to high energy photon beams, the overall integral non-target dose is reduced in proton beam therapy. Imaging studies for treatment planning and the process of delineating target volumes and structures of interest are the same for proton therapy as for conventional photon beam therapy.

TREATMENT DELIVERY

Patient Positioning, Immobilization and Motion Management

The very advantage of proton therapy as a highly target-conformal treatment modality also makes it susceptible to geographical misses. Therefore, immobilization and daily verification of set up are essential. Translational error as little as 1 mm and rotational error as small as 0.5 degrees can be detected and corrected by imaging. Additional concern for proton and other charged particle beam therapy is that the particle range is affected by internal organ motion into and out of the beam. For example, in prostate treatments, the position of the Bragg peak may be significantly altered if parts of the pelvic bone move into the beam, which can happen if, during the treatment, the pelvis is rotated compared to the simulated planned position.

Relative Biological Effectiveness (RBE)

Biologically, protons are slightly more effective than photons. The relative biological effectiveness (RBE) of particles is defined as the dose of reference radiation divided by the proton dose to achieve the same biological effect. Use of the RBE allows radiation oncologists to prescribe an appropriate dose for proton beam therapy based on the large pool of clinical results obtained with photon beams. At present, proton therapy is based on the use of a single RBE value of 1.1 at almost all institutions, independent of dose/fraction, position in the SOBP, initial beam energy or the particular tissue. The recent AAPM report 256 (2019) concluded that the value of 1.1 "is not well justified. Considering the uncertainties in quantifying and modeling RBE effects in various tumor and normal tissues for various endpoints, it is premature to adopt and recommend a variable RBE model to use clinically."

STATE LICENSING/REGISTRATION REVIEW

The reviewer from the state radiation control program will need to consider the following items in the application as discussed in these sections.

STAFF QUALIFICATIONS & TRAINING

In addition to ensuring compliance with State regulations for licensed professionals, the reviewer should also ensure that the staff meet currently accepted professional body standards for proton therapy, such as ACR-ASTRO and ACR-AAPM. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Proton-Therapy-RO.pdf; https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Proton-Therapy-TS.pdf

Radiation Oncology Physician

Meet state requirements to practice medicine and provide evidence of radiation oncology training and experience, including proton beam therapy.

Qualified Medical Physicist (QMP)

Meet state requirements to practice therapeutic medical physics and provide evidence of training to carry out all tasks related to the physics and safety aspects of the machine and model, including acceptance testing, commissioning and calibration, treatment planning and quality assurance testing. The training may be provided by a vendor or documented training and experience from a qualified proton therapy physicist.

Dosimetrist

Meet state requirements for treatment planning and other duties assigned by the facility, with evidence of training in proton beam treatment planning.

Radiation Therapist

Meet state requirement to operate radiation therapy equipment in a clinical setting and provide evidence of training to treat on the proton beam unit at the facility.

SITE PLAN

Shielding Design Plan

Radiation Safety, Production of Secondary Radiation, Shielding Considerations

The goal of radiation shielding is to attenuate the radiation produced in the proton beam accelerator, beam transport system and treatment room components, in order to protect patients, medical staff, and members of the public. In proton beam systems, the production of neutrons is of significant concern. The shielding design must be adequate to protect personnel from the secondary neutron field generated during proton beam therapy. The application must also address associated safety hazards from beam losses requiring facility shielding, activation of various treatment unit components and resulting radioactive decay and secondary radiation reaching the patients.

About 20% of the protons incident on the patient have nonelastic interaction with the nuclei of the target atoms. These interactions give rise to charged particles such as protons, deuterons, alpha and recoil nuclei, where 60% of the energy released is absorbed locally, and neutral particles such as neutrons and gammas, where 40% of the energy are absorbed by the surrounding matter. In addition, these nuclear interactions can produce unstable recoil nuclei (activation).

For shielding purposes, protons and neutrons are the most important secondary particles from nuclear interactions because they can carry energy far from the point of interaction. Activation of components in the beam transport system is of concern in proton beam therapy installations. The aperture, the compensator, and even the patient are sources for the production of neutrons. Minimizing the amount of energy-degrading material in the beam path in the nozzle can help minimize neutron production. Prompt radiation can expose both staff and the public and can be controlled by proper shielding. Activation due to proton and neutrons poses exposure to staff and particularly to maintenance personnel. These exposures should be minimized by procedural controls and should be monitored through the use of personnel dosimeters. Activation can also result in emission to the environment. Procedural control through proper disposal of activated waste and effective ventilation is required as well for proton beam therapy centers.

Specific Regulatory Dose Limits for All the Controlled Areas and the Uncontrolled Adjacent Areas

Map of Treatment Facility Layout

Accelerator, beam transport corridor(s), treatment room(s) and research use area(s), adjacent occupancies, type of area (controlled, uncontrolled, public), above ground/underground.

Treatment Room

Dose limits are the same regardless of design, using maze or mazeless with sliding or rotating doors.

Occupancy Factors

Take into account the amount of time the irradiated areas are occupied by radiation workers or members of the general public and should follow currently accepted practices and standards and may be found in *NCRP Report No. 151, Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities.* https://ncrponline.org/publications/reports/ncrp-reports-151/

Regulatory Dose Limits

Limits used to design and evaluate shielding may be found in federal/state regulations and International Atomic Energy Agency (IAEA) *Safety Reports Series No. 47 Radiation Protection in the Design of Radiotherapy Facilities.* https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1223_web.pdf

Accelerator, Treatment, and Beam Parameters

- Specify accelerator type: synchrotron/cyclotron/synchrocyclotron
- Particle type (proton)
- Energy range (e.g., 70 – 235 MeV)
- Beam current at maximum energy to deliver a specific dose rate, in nA and corresponding particle rate protons/sec) (e.g., 10 nA, corresponding to approx. 6 x 10^{10} protons/sec.)
- Average power (beam on) (kW)
- Repetition rate (Hz)
- Duty factor (beam on time)
- Conformal beam, beam delivery (scanning vs. scattering, other types), and directionality
- Estimated number of patients per year
- Estimated maximum and average tumor volume (cc)
- Estimated number of treatment fractions per patient at each energy
- Dose delivered per fraction
- Beam-on time per fraction
- Beam field size
- Beam loss and location of loss

Shielding Design and Material: Composition/Density/Water Content

The construction materials and each of their associated dimensions (height and thickness) for all structures (wall, floor, ceiling, mazes) are needed. Specifically, identification and specifications of any non-concrete materials present in the walls of the treatment rooms are needed. Manufacturer's data sheets for all shielding materials should be included.

The composition of the shielding materials need to be specified. Concrete provides the best structural material and is comparatively inexpensive for shielding. Shields made up of layers of iron and steel or mixtures of concrete and polyethylene may provide more attenuation of neutrons per unit thickness than concrete shielding alone. However, these composite materials may not possess adequate mechanical integrity and need additional support structures.

The source terms for shielding calculation may be provided by the manufacturer or derived from experiments carried out under clinical conditions, as well as from simulations. Exposure levels may be affected by changes in operating conditions and assumptions. All the treatment rooms must have both the horizontal and vertical dimensions, with neutron source and dose calculation points specified. The neutron dose equivalent needs to be assessed for different beam orientations.

The supporting concrete slab is designed to prevent neutron groundshine. Also, any special provisions to the roof structure to prevent the escape of neutrons to the outside environment should also be addressed in the shielding design.

Consideration for Shielding of Secondary Radiation

Protons slowing down in matter undergo nuclear interactions producing secondary radiation consisting of photons and neutrons and other nuclear fragments. Shielding against neutron radiation is therefore important for any proton therapy installation. The report should address shielding of imaging control booths that are situated within treatment rooms and storage-for-decay of spent devices (where applicable, e.g. brass apertures) and activation of material along the entire path of the beam to meet regulatory compliance regarding radioactive material inventory.

The application should specify plans for radiation survey and monitoring, including the ability of the equipment (multiple detectors/survey meters) to detect photons, neutrons, and contamination from activation. Personnel and area exposure monitoring should be carried out with National Institute of Standards and Technology (NIST) traceable dosimeters such as thermoluminiscent dosimeter (TLD)/OSLD/ optically stimulated luminescent dosimeter (OSLD) and neutron badges.

OTHER REQUIREMENTS BY THE STATE

Radiation Survey, Monitoring, and Survey Equipment

- Calibration reports for both neutron and photon survey meters
- Prior to clinical use, evaluation of shielding prior to commissioning and after any change in the structure

Radiation Safety Program for Routine Survey and Monitoring

Monitoring Equipment

- National Institute of Standards and Technology (NIST) traceable dosimeters such as TLD/OSLD/neutron badges and alarm systems in controlled and supervised areas, e.g. console
- Personnel protection system
- Gantry rooms equipped with emergency buttons (stop proton beam and gantry/table motion)
- Last man out procedures
- Interlocks (IL) in place
- Audible/visual communication and indicators
- Static warning signs

SUMMARY OF SHIELDING CONSIDERATIONS

Radiation protection in proton therapy is mainly an activation and neutron shielding issue requiring consideration of:

- High energy secondary neutrons
- Activation of parts, air, soil and building
- Area monitoring with mobile neutron and photon survey detectors and NIST traceable dosimeters such as TLD/OSLD/neutron badges
- Personnel dosimetry and protection system

Accounting for Skyshine, Groundshine, Ducts, and Penetrations

The shielding design should indicate any and all intrusions through the treatment wall. This would include the nature of the intrusion, composition of the intrusion (boron treated steel pipe), angles or bends associated with the intrusion (e.g. bends in the pipe) and any special shielding design that would be employed. Radiation measurements may reveal hidden flaws, such as the failure to survey conduits or cracks or changes in the concrete density due to the absorption or evaporation of water content.

Shielding Site Survey for Verification

Review and Verification of Assumptions and Calculations

Long-term monitoring is needed to verify dose equivalent values that are based on the actual clinical workload for ensuring compliance with the regulatory dose limits. The application will show a summary of the measured dose rates during a fixed acquisition period and the calculated dose rates for a specific operating beam current and energy in the proton beam incident on a target.

In summary, the application should include beam operational conditions, including but not limited to: beam-stop location, beam-stop composition, proton beam current, and incident proton energy. Measurements are made at each of the specified locations above for the neutron dose equivalent values at that location. In this way, an application reviewer can determine if the shielding is adequate to meet the radiological safety requirements of the occupationally exposed workers and the general public.

The regulatory agency should arrange to have staff accompany the facility's shielding professional and/or Radiation Safety Officer early during the construction process to observe as well as during the radiation protection survey after completion. Visits during construction and post construction serve to educate and inform state radiation control program staff and also function as an independent set of eyes that can help mitigate mistakes that may be expensive to correct.

Evaluation of the appropriateness of clinical management of patients is outside the scope of state radiation control programs and the staff's ability. Reports of accreditation survey or independent physician and physicist audits may help inspectors to determine if the facility is meeting currently accepted standards of care.

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ACRONYMS

AAPM	American Association of Physicists in Medicine
ACR	American College of Radiology
ASTRO	American Society for Radiation Oncology
AVF Cyclotron	Azimuthal Varying Field Cyclotron
CBCT	Cone Beam Computed Tomography
CT	Computed Tomography
IAEA	International Atomic Energy Agency
ICRU	International Commission on Radiation Units and Measurements
IL	Interlock
IMPT	Intensity Modulated Proton Therapy
IMRT	Intensity Modulated Radiation Therapy
IAEA	International Atomic Energy Agency
MCL	Multi-leaf Collimators
MRI	Magnetic Resonance Imaging
NCRP	National Council on Radiation Protection
NIST	National Institute of Standards and Technology
OBI	On Board Imager
OSLD	Optically Stimulated Luminescent Dosimeter
P&P	Policy and Procedure
PET	Positron Emission Tomography
QMP	Qualified Medical Physicist
RF	Radiofrequency Range
R&V	Record and Verify
RBE	Relative Biological Effectiveness
RLSP	Relative Linear Stopping Power
SOBP	Spread Out Bragg Peak
TLD	Thermoluminiscent Dosimeter
TPS	Treatment Planning System
US	Ultrasound Scanner
USNRC	United States Nuclear Regulatory Commission

GLOSSARY

Azimuthal Varying Field (AVF) Cyclotron
Horizontal angular distance from a reference direction.

Beam Penumbra
The decrease at the edges of the radiation beam.

Bragg Peak
Region of the highest energy transfer of the proton beam – located near the end of its range.

Calibration
In the context of radiation oncology, calibration refers to (1) an accurate determination of the response to incident radiation of a measurement instrument such a survey meter or an ion chamber and electrometer system and (2) an accurate measurement of the output of a radiation producing device such as an accelerator or a radioactive source.

Compensator
Device (either standard or custom made) used to account for irregularities in body surfaces by providing a differential attenuation of the radiation beam before it reaches the patient, in order to produce more uniform and desirable dose distribution in and around the treatment volume.

Groundshine
Radiation that has gone through the floor and scattered back upwards in the ground is known as groundshine.

Intensity Modulated Radiation Therapy (IMRT)
A technology that uses multiple beams of varying intensities to treat cancer.

Intensity Modulated Proton Therapy (IMPT)
A technology that delivers modulating intensity of a proton beam to match the contours of a tumor.

Interlock (IL)
A barrier, mechanical, electrical or software, or way to prevent an action if certain conditions are not met by mechanical or electrical or software.

Isochronous Cyclotron
The orbital period is the same for all particles regardless of their energy or orbital radius.

MeV
Million electron volts, the unit used for specifying the energy of the electron and other particle beams used for therapy.

Modulation
In the context of proton beam therapy, varying the number and depth of several Bragg peaks that are weighted differently, so as to produce a uniform dose region over the intended target volume.

Multi-leaf Collimators (MLC)
Technology that uses opposed pairs of narrow leaves positioned between the primary collimator and the treatment head of a therapy machine. These leaves, made of a high atomic number material, such as tungsten, are computer controlled and may be programmed for each gantry angle to assume the desired shape to conform to the shape of the intended treatment volume, allowing maximizing target dose while reducing the minimizing dose to adjacent healthy tissues and critical structures.

National Institute of Standards and Technology (NIST)
A physical science laboratory and agency in the U.S. Department of Commerce.

Optically Stimulated Luminescent Dosimeter (OSLD)
A dosimeter that measures radiation dose by the luminescence the aluminum oxide doped with carbon in the dosimeter produces when stimulated with light.

Pencil Beam
A pencil beam is a geometric construct used to describe a beam of electromagnetic radiation or charged particles, usually in the form of a narrow cone or cylinder.

Policy and Procedure (P&P)
Policy and procedure developed and implemented by the facility to address all aspects relating to the patient, worker, and public safety, facility operation and treatment planning, delivery and follow up care.

Prompt Radiation
Radiation produced only when the beam is on, from interaction of the proton beam with any material in its path starting from the accelerator to the patient's body.

Range Modulator
A physical device such as a modulation wheel or a ridge filter used to produce a Spread Out Bragg Peak (SOBP).

Range Modulation Wheel
A modulator wheel combines absorbers of various thicknesses in a circular rotating track to produce a temporal variation of the beam energy.

Range Shifter
A physical device of uniform thickness that is used to "pull-back" range by a specific amount. This device is typically used downstream and close to the patient with pencil beam delivery.

Relative Biological Effectiveness (RBE)
In radiation biology, the ratio of the doses by two different radiations to cause the same level of biological effect.

Relative Linear Stopping Power (RLSP)
Defines the range of protons in tissue, obtained from CT for different density phantoms and using established conversion curves.

Scattering Systems
The proton beam is spread across the treatment volume by placing a scatterer in its path. A single scatterer is sufficient for small field sizes. Dual scattering is needed to achieve larger field sizes. This method of spreading the beam is termed passive as opposed to scanning.

Scanning Systems
Under computer control, a narrow spot beam of protons is deflected and steered magnetically (scanned) to cover the extent of the treatment volume and the desired depth of penetration achieved through the choice of energy before the beam enters the gantry.

Skyshine Radiation
Radiation that goes over the roof and scatters in the air towards the ground is known as skyshine.

Spread Out Bragg Peak (SOBP)
Modulation of beam energy to produce a region of uniform dose to conform to the volume intended for treatment.

Synchrotron
A circular accelerator ring. A beam of protons injected into the ring is accelerated further by electromagnetic resonant cavities around the ring, gaining energy during each circulation. The magnetic field strength is varied (or synchronized) with the particle energy to steer the particles in the ring, hence the name synchrotron.

Synchrocyclotron
A special type of cyclotron that allows for the frequency of the alternating voltage to be varied to match that of the orbiting particles.

Thermoluminiscent Dosimeter (TDL)
A radiation dosimeter that measures ionizing radiation exposure by measuring the intensity of visible light emitted from a sensitive crystal in the detector when the crystal is heated.

Wobbling
In proton beam therapy, a relatively broad beam (about 5 cm diameter), instead of a pencil beam, scanned magnetically across the target volume. Larger field sizes can be produced at depth this way, as compared to passive scattering.

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APPENDIX A
INSPECTION BY STAFF FROM STATE RADIATION CONTROL PROGRAMS

TRAINING FOR INSPECTORS

This document provides an overview of the basic physics underlying proton beam therapy and the types of accelerators in use at the time of this writing (2019). Since technology advances and implementation in healthcare are rapid, it is important for state radiation control program staff to stay informed on changes in standards and treatment delivery. In addition, inspectors can and should request facility staff to explain the items they are testing and tolerances and limitations of validation. Understanding the capabilities and limitations of technology is required for state government staff to develop appropriate regulations, provide guidance and ensure compliance, quality of care and radiation safety. The checklist in Appendix B is meant as a guide and can be edited to suit the state's regulations.

Independent dosimetry verification should be obtained prior to clinical use. Also, disease-site specific dosimetric measurements should be made prior to treating patients on a new machine, or after major modification to the beamline, or using a new or updated treatment planning system.

Commissioning and validation of new or updated treatment planning systems should be performed following established protocols recommended by the AAPM or *IAEA (TRS 430, TECDOC-1583). Commissioning of Radiotherapy Treatment Planning Systems: Testing for Typical External Beam Treatment Techniques.*
https://www-pub.iaea.org/MTCD/Publications/PDF/te_1583_web.pdf
The Commissioning report, including end to end verification, is recommended to be reviewed independently.

Evaluation of the appropriateness of clinical management of patients is outside the scope of radiation control programs and the staff's ability. Reports from an accreditation survey or independent physician and physicist audits may help inspectors to determine if the facility is meeting currently accepted standards of care.

INSPECTION FREQUENCY

Inspection frequency is set by the state regulations. Inspection of radioactive materials licensees is usually unannounced. However, a 24-hour notice would help ensure that representative staff from the different teams involved in proton therapy is available to meet with the inspector on the day of the inspection.

Prior to the Inspection

The inspector should review recent correspondence from the facility and bring the following: calibrated survey meter(s), registration/license file, copy of checklist and a printout of the floor plan.

Request Interview with Staff Representatives

Some questions/items in the checklist are answered or explained best by staff with particular expertise. It is preferable to make the request soon after arriving on site and schedule them to accommodate staff availability.

- Radiation Oncology Physician
- Qualified Medical Physicist
- Dosimetrist
- Radiation Therapist
- Clinical Engineering
- Facility Administration

Request a Tour of the Center

The inspector should request a tour of the center in a way that does not interrupt clinical workflow. Note any changes to floor plan/operation compared to the one on file.

APPENDIX B
INSPECTION CHECKLIST

The inspection checklist addresses the following items. States are encouraged to review this list and the checklist and tailor the checklist to suit their requirements.

INITIAL

- Acceptance Testing
- Commissioning
- Beam Output Calibration Verification
- Staff Qualifications and Training
- Radiation Safety and Protection

ROUTINE

- Quality Assurance (QA)
- Patient Medical Records
- Staff Qualifications and Training, Initial and Annual
- Radiation Safety and Protection

CHECKLIST FOR INSPECTION

PROTON RADIATION THERAPY EQUIPMENT

(Complete one form of this section for each unit reviewed)
Identification of Unit Manufacturer and Model and Serial Number
Proton Energies Available/Used
Number of Rooms and Room Number/ID (A, B, C or 1, 2, 3 etc.)
Machine Type: Synchrotron/Synchrocyclotron/Cyclotron/Other

Equipment

		YES	NO
1)	The control panel displays beam parameters (range, modulation, mu)	☐	☐
2)	The treatment head/attachments/accessories/nozzle secure and stable	☐	☐
3)	There is an easily discernible "BEAM ON" indicator on the control panel	☐	☐
4)	A suitable exposure control device/independent beam monitor device in place to terminate the exposure automatically after a preset time interval or dose limit	☐	☐
5)	Means provided to allow operator to terminate the exposure at any time	☐	☐
6)	Emergency switches to stop gantry/table motion at any time	☐	☐
7)	High Radiation Area Signs posted on door of treatment room(s)	☐	☐

Structural Shielding

		YES	NO
1)	All protective barriers, except the treatment room door, are fixed in position	☐	☐
2)	The therapy beam control panel is located outside the treatment room	☐	☐
3)	Imaging control panel is located inside/outside the treatment room, shielded	☐	☐
4)	Shielding adequate: Initial calculations	☐	☐
	Survey confirmation	☐	☐
5)	Equipment activation survey done annually	☐	☐
6)	Neutron survey done annually	☐	☐
7)	Survey documents available for review	☐	☐

Conditions for Operation of Equipment

		YES	NO
1)	The radiation output calibrated prior to start of clinical use	☐	☐
	a) The calibration double checked independently prior to start of clinical use	☐	☐
	b) The method of calibration in accordance with currently accepted protocol	☐	☐
	Specify IAEA TRS 398 or other, specify________________________________		
	c) After the initial calibration, the unit calibrated annually and after any change or repair which could affect output	☐	☐
	d) The calibration performed by a person who met the requirement of state regulations. (Board: State License #)	☐	☐
2)	P & P to allow only the patient in the treatment room during treatment	☐	☐
3)	P & P to allow treatment only when door interlock functional (Door interlock functionality may be tested by inability to turn beam on with door open.)	☐	☐
	a) The interlocks are arranged so that treatment cannot be restarted without the controls being reset	☐	☐
	b) Collision sensors on the treatment room door	☐	☐
	c) Collision sensors on the treatment room door functional	☐	☐
4)	P&P to prohibit treatment if patient cannot be observed continuously	☐	☐
	a) Video monitoring of patient functional	☐	☐
5)	P&P to prohibit treatment if aural communication with patient not functional	☐	☐
	a) System for aural communication with the patient functional	☐	☐
6)	Readily observable or discernible signals which indicate the production of radiation located near the outside of each treatment room door	☐	☐

PROTON RADIATION THERAPY PROCESS

Quality Assurance

		YES	NO
1)	Patient's evaluation and intended treatment documented in the patient's record	☐	☐

		YES	NO
2)	Prescription, a signed and dated order (written directive) (site, energy/modality, technique, dose per fraction, number of fractions and total dose)	☐	☐
3)	All orders and other treatment records are clear and legible		
4)	Staff instructed to obtain clarification if order is confusing	☐	☐
5)	Patient's response to treatment is assessed by qualified radiation oncologist (weekly physician progress notes) ☐ ☐		
6)	Complete treatment records, data recorded at the time of each treatment ☐ ☐		
7)	Charts of patients undergoing fractionated treatment are checked for completeness and accuracy at least once every 5th treatment (weekly physics check)	☐	☐
8)	Double checks of treatment plan and related calculations prior to treatment (QMP using independent method or a second person verifying the plan and calculations)	☐	☐
9)	Treatment plans approved by radiation oncologist prior to treatment and after any change (proton therapy trained radiation oncologist)	☐	☐
10)	Software interlock to prevent treatment without double checks and radiation oncologist approval if the R&V system allows electronic approvals by QMP and radiation oncologist	☐	☐
11)	Deviation from standard treatment protocols highlighted in the treatment record and R&V and available at the console	☐	☐
12)	Quality control for all physical components of radiation therapy:		
	a) Chamber and electrometer, survey meters (initial and periodic calibration)	☐	☐
	b) Planning equipment (x-ray, fluoroscopic, CT, MRI, US, PET/CT)	☐	☐
	c) Treatment verification and guidance equipment (CBCT, OBI, US, MRI, other)	☐	☐
	d) Treatment planning computer	☐	☐
	e) Patient dose monitoring, if in use	☐	☐
	f) Vendor guidelines, AAPM/IAEA recommendations	☐	☐

		YES	NO
13)	Quality control tests to be performed are documented, including:		
	a) Detailed procedures for performing each test	☐	☐
	b) The frequency of each test	☐	☐
	c) Acceptable results for each test	☐	☐
	d) Corrective actions taken if outside tolerance	☐	☐
	e) Record keeping and reporting procedures for test result	☐	☐
	f) Items checked and frequencies conform to vendor and/or IAEA/AAPM guidelines	☐	☐
14)	P&P to ensure matching of treatment delivered to plan approved and intent indicated in the initial consult note and documentation of any differences	☐	☐
15)	System to ensure different treatment parameters on different days (dose, energy, treatment aids such as bolus on alternate days) adequate	☐	☐
16)	P&P Manual reviewed and revised if regulations revised since last inspection	☐	☐
17)	P&P for beam interlock override by therapists	☐	☐
	Overrides documented with names and reasons and reviewed by physicist	☐	☐
18)	P&P for use of personal electric devices while treating patients	☐	☐
19)	Equipment PM, service and failure, records available	☐	☐

SOFTWARE

New software/hardware since last inspection, specify________________________________	☐	☐
P&P, QA and training records for new software/hardware/modality	☐	☐

DOSIMETRY

Treatment Planning System(s), specify_________________________________		
Commissioning and Validation by QMP?	☐	☐

		YES	NO
1)	Acceptance by QMP	☐	☐
2)	Beam data entered into the TPS verified	☐	☐
3)	Includes calculation methods and algorithms used at the facility	☐	☐
4)	Reviewed by QMP initially, annually and after upgrades/changes	☐	☐
5)	Training records available initially and after upgrades/changes	☐	☐
	P&P for Weekend/off hour calculations by MDs, RTTs	☐	☐
6)	Training and orientation records for new staff and new systems both hardware and software	☐	☐
7)	CT number vs. RLSP data in the TPS verified annually	☐	☐

AUDITS & ACCREDITATION

Required by the State: **Yes/No**

		YES	NO
1.	Accredited	☐	☐
	From________________ To___________		
	Application submitted	☐	☐
	Report available for review	☐	☐
	Accrediting Body, specify_________________________		
2.	12 month audits	☐	☐

		YES	NO
	Auditor Physician: Board: Qualified	☐	☐
	Current active practice in Proton beam therapy?	☐	☐
	Auditor Physicist: Board: Qualified	☐	☐
	Current active practice in Proton beam therapy?	☐	☐
3.	Facility promptly reviewed audit findings, documented actions or reason why actions were not acted upon.	☐	☐
4.	Maintains written records of QA and audit activities for State review.	☐	☐

SUMMARY OF AUDIT ACTIVITIES - PLEASE ATTACH ADDITIONAL SHEETS AS NECESSARY EQUIPMENT

Additional equipment		QA Manual		QA Records	
		YES	NO	YES	NO
Simulator	Make/Model/Serial No._____	☐	☐	☐	☐
CT Sim	Make/Model/Serial No.	☐	☐	☐	☐
CT	Make/Model/Serial No._____	☐	☐	☐	☐
MRI	Make/Model/ Serial No._____	☐	☐	☐	☐
Ultrasound	Make/Model/Serial No._____	☐	☐	☐	☐
Other	Make/Model/ Serial No._____	☐	☐	☐	☐

Inspector should review QA records of all equipment used for planning and guiding treatment. If imaging equipment used for treatment planning is owned/operated by a different entity, the inspector should interview physics staff to learn how they ensure that equipment used for treatment planning is functioning as intended. If it is not their equipment, it may be adequate for the facility to obtain a copy of the annual QA and QA done after major service/repair work.

SCHEMATICS

	YES	NO
Schematics of accelerator, beam transport, beam delivery systems available	☐	☐

There are numerous safety interlocks in a proton beam accelerator. The inspectors may not be able to test them. Interviews with both the physics and therapist staff would help the inspector determine if there are adequate Policies and Procedures and request to see evidence of periodic reviews of the interlock performance by staff. Testing of door interlocks for proton therapy may need to be designed without compromising system reliability. Systems may be designed to go into emergency mode to insert beam stops into the beamline that can reduce component life expectancy. Consider test for inability to turn beam on with door open as acceptable alternative.

List of Interlocks (IL)	IL1	IL2	IL3	IL4	IL5
Accelerator Test/Functional					
Beam Transport Test/Functional					
Beam Delivery Test/Functional					

	YES	**NO**
Record of IL Triggers	☐	☐
Investigation/Resolution	☐	☐
P&P for responding to beam alerts/interlocks	☐	☐

ADMINISTRATION

Facility Administration/Operation/Emergency Response Systems

		YES	**NO**
1)	Emergency power switch for superconducting magnet system (where applicable)	☐	☐
2)	Radiation registration certificates/tags for accelerator, imaging generator posted	☐	☐
3)	Radiation safety officer contact information posted	☐	☐
4)	QMP contact information posted	☐	☐
5)	Clinical engineering contact information posted	☐	☐
6)	Facility/building management contact information posted	☐	☐

Workload and staffing levels

1) Number of patients per day	
2) Number of patients per year	
3) Pediatric patients per year	
4) Adult patients per year	
5) Number of therapists on the machine	FTE
6) Number of proton therapy physicists	FTE
7) Number of dosimetrists trained for proton therapy planning	FTE
8) Physics assistants/Junior Physicists/Physics Residents	FTE

9) Physicians/Physician Residents	FTE
10) Nurses	FTE
11) Anesthesiology nurses/physicians	FTE
12) Clinical engineering	FTE
13) Other staff specify	FTE

EXPOSURE RECORDS

Staff Exposure Records	**YES**	**NO**
Personnel Monitoring Vendor ______________________	☐	☐
Frequency __________________	☐	☐
Reports reviewed by the RSO	☐	☐
Unusual exposures investigated and resolved	☐	☐
Staff provided summary of annual exposure history	☐	☐
Declared pregnant worker employee exposure monitoring records adequate	☐	☐

Radiation Shielding and Evaluation Survey Additional Notes	**YES**	**NO**
Shielding survey prior to clinical use	☐	☐
Activation assessment, survey (annual)	☐	☐
Area exposure monitors (photon, neutron, activation/contamination)	☐	☐
Secure storage of apertures or QA equipment activated by the beam.	☐	☐

INSPECTOR'S SPOT CHECKS

Survey meter used ______________________
Calibration Date ______________________
Indicate points where survey was done on the facility diagram sheets.

STAFF INTERVIEW

Title	Name
Radiation Oncology Physician	
Qualified Medical Physicist	

Dosimetrist
Radiation Therapist
Clinical Engineer
Facility Administrator

	YES	NO
Summary of Equipment QA activities and records available	☐	☐

Summary & Items/issues for Exit Meeting

EXIT MEETING

Facility Name

License/Registration Number

Date of inspection

Inspector(s)

List facility attendees

Name **Title**