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Performance Specifications for Proton Medical Facility

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Abstract

Performance specifications of technical components of a modern proton radiotherapy facility are presented. The technical items specified include: the accelerator; the beam transport system including rotating gantry; the treatment beam-line systems including beam scattering, beam scanning, and dosimetric instrumentation; and an integrated treatment and accelerator control system. Also included are treatment ancillary facilities such as diagnostic tools, patient positioning and alignment devices, and treatment planning systems. The facility specified will accommodate beam scanning enabling the three-dimensional conformal therapy delivery.

Performance Specifications for Proton Medical Facility

In recent years, there has been a heightened interest among the worldwide medical community for dedicated, hospital-based proton facilities to treat cancer and other diseases. These proton facilities must have the following capabilities:

- to treat most of the tumors — related to longest and shortest penetration depths of proton beams and achievable field sizes
- short treatment time — beam intensity at the patient
- with desirable physical characteristics of the proton beams — sharp delineation of the treated volume from the surrounding healthy tissues that have to be protected, or the uniformity of the dose within the treated volume
- versatility of the treatment delivery — fixed and movable beams to provide entry of the beam into the patient from any arbitrary direction specified by therapy planning
- optimized patient flow through the treatment facility — multi-room operation, high efficiency of beam use, and supporting ancillary facilities
- patient safety — accurate dosimetry and reliable control system.

The clinical specifications summarized in Section C define the desired facility. We believe that technologies exist today to meet all of the requirements; however, it is a challenge to meet all the requirements within a reasonable budget. Under such circumstances, it is crucial to understand the technical performance specifications called for by these clinical specifications, and the tradeoffs among possible technical solutions. The technical performance specifications given here provides some answers and guidance to these processes.

We have tried to keep the performance specifications general, *i.e.*, not to choose a particular technology or specify machine parameters in detail. We have presented some strawman configurations as illustrations or design examples, such as for the accelerator or a beam transport system. We emphasize that they are presented purely as examples of possible technical solutions.

This performance specification document is structured as follows:

- A. General Introduction
- B. Format of Performance Specifications
- C. Clinical Specifications
 - 1. Specifications for General Facilities
 - 2. Performance Specifications for Synchrotron Accelerator Systems
 - 3. Performance Specifications for Beam Transport Systems
 - 4. Performance Specifications for Treatment Beam Line (Nozzle)
 - 5. Performance Specifications for Integrated Treatment and Accelerator Control System
 - 6. Performance Specification for Treatment Ancillary Facilities

A. General Introduction

Proton therapy offers a unique opportunity for precise, localized irradiation for treatment of cancer and other diseases. There is greater deposition of radiation dose in the tumor than is possible with conventional radiotherapy and more sparing of adjacent critical normal tissues. The use of charged particles such as protons and helium ions in medicine has been pioneered over four decades at the Lawrence Berkeley Laboratory and the University of California, San Francisco Medical Center.¹ With the success of these initial studies, charged particle radiation treatment has now spread to facilities in additional countries including Japan, France, Switzerland, United Kingdom, Sweden, South Africa and Russia with planning for its use in several others. In the US, the Harvard Cyclotron has developed a similar program for proton treatment² and more recently, proton therapy has begun at the Loma Linda University Medical Center.³

The use of proton therapy in the treatment of human disease requires skilled medical and physical application of complex techniques in selecting and preparing patients for therapy, treatment planning in 3-D, careful measurement of beam parameters, and precise, accurate delivery of radiotherapy. Not all cancer patients are

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- ¹ J. R. Castro, J. M. Quivey, J. T. Lyman, G. T. Y. Chen, T. L. Phillips and C. A. Tobias, *J. Assoc. Canad. Radiol.* 31, 30-34 (1980).
 - ² H. D. Suit, M. Goitein, J. Munzenrider, L. Verhey, M. Urie, E. Gragoudas, A. Koehler, B. Gottschalk, J. Sisterson, H. Tatsuzaki and et al., *Strahlentherapie und Onkologie* 166, 40-44 (1990).
 - ³ J. M. Slater, J. O. Archambeau, J. D. Slater, I. Neilsen and W. Preston, "An integrated hospital-based facility for proton beam radiation therapy," *Proc. of the NIRS International Workshop on Heavy Charged Particle Therapy and Related Subjects* (ed. by A. Itano and T. Kanai), July 1991, Chiba, Japan, 82-91 (1991).

likely to demand such high technology proton therapy but for those who do, such treatments usually represent the best or often the only curative treatment modality. A concerted effort is underway to further study and refine the applications of proton therapy and to make this treatment available to more patients.

Already, the research studies carried on for many years at LBL and UCSF by a dedicated team of physicians, physicists, biologists and allied scientists have found promising results in the treatment of tumors in the eye, orbit, skull base, paranasal sinuses, nasopharynx, juxtaspinal area, retroperitoneum, bone, soft tissues and prostate gland.⁴ For many of these patients, no other surgical or medical therapy, including other forms of irradiation, has been effective as proton therapy. Radiation tumor dose increases of 10-35% over standard techniques are achieved and, as predicted, have significantly improved tumor control and survival.

There is a growing need for flexible, clinically optimized hospital-based accelerators that can pursue further studies in optimization of proton therapy, extend its use to other tumors, and make this therapy available to larger number of patients. The National Cancer Institute is supporting efforts to plan for such additional facilities and to engage in cooperative clinical research trials to determine fully the role and extent of proton therapy needed in the US. Among the goals of these cooperative research trials are to optimize treatment techniques, determine which additional tumors are well treated with protons, assess the availability and need for proton therapy nationally and explore combining proton therapy with other treatment modalities.

Several regionally based proton therapy centers are needed to conduct this clinical research and meet the needs of the nation for charged particle therapy. Each should be carefully planned to provide clinically optimized proton radiotherapy over an expected facility lifetime of 25-30 years, allowing for improvements in physical parameters and medical utilization during this period.

The clinical and technical performance specifications in this document have been developed through extensive discussions among the LBL staff and with collaboration from many outside experts. They are intended to assist in the design and planning of a state-of-the-art medical proton therapy facility to meet the requirements stated above.

⁴ J. R. Castro, *Treatment of Cancer with Heavy Charged Particles*, Lawrence Berkeley Laboratory, February 1991, PUB-5301 (1991).

We expect such proton radiotherapy facilities to provide the best in medical therapy for the twenty-first century.

B. Format of Performance Specifications

In this document, complete technical performance specifications of a future proton medical facility are presented. The items specified include:

- Sec. 1: the proton medical facility in general
- Sec. 2: the accelerator complex
- Sec. 3: the beam transport system including the gantries
- Sec. 4: the proton treatment beam lines (nozzles) including beam-delivery systems and monitors
- Sec. 5: the integrated treatment and accelerator control system
- Sec. 6: ancillary facilities including the therapy planning

The treatment-room associated ancillary facilities, such as patient setup room, immobilization pod storage room, treatment console area for radiation therapists, patient waiting, dressing rooms, and other facilities, are not specified in this document as they are specified in the Building Specifications Document of the facility.

The format of the Performance Specifications is as follows

##.##. Descriptive heading of specification: The main specifications are presented in boxes for easy identifications. They are numbered in a structured way to facilitate cross-reference.

The specifications that can be expressed best in tables are shown following the boxed specification statement. An explanation or amplification of the specification also follows the boxed specifications. Referring to related specifications are expressed in [##.##]. When pertinent, design examples and suggestions for solutions are given.

These performance specifications have the same weight as the Clinical Specifications, and when a conflict exists between the Clinical Specifications and the Performance Specifications, the tighter requirement will prevail.

Other supplementary documents necessary to understand the performance specifications of the proton medical facility are appended to this document

C. Clinical Specifications for Proton Treatment Facility

We provide below a set of clinical specifications to develop technical performance specifications for acquisition of technical components. This list is compiled based on the joint LBL/UCD-MGH clinical specifications document,⁵ by editing and replacing the preferred/minimum specifications with a single set of specifications.

C-1 Range in patient: 3.5 g/cm² - 32 g/cm² for fields smaller than 22 cm × 22 cm

Range in patient (which will be specified as g/cm² in water-equivalent thickness) is a function of the initial beam energy from the accelerator [2.1.1] and the amount of material in the beam between the accelerator and the patient. These include vacuum windows, beam monitoring devices [3.5.2, 4.1.3] and any devices associated with beam spreading [4.1.1] and range adjustment [4.1.4]. A 250 MeV proton beam has a range of 38 g/cm² in water. Note that a passive scattering system will cause a significant loss of range if large field sizes are combined with a short SAD (effective source to axis distance). The full range of 32 g/cm² is not required for all field sizes; for larger field sizes (≥ 22 cm × 22 cm) the minimum acceptable range is 22 g/cm². Also note that the smallest required range for extracted beam is about 3.5 g/cm² corresponding to an energy of about 70 MeV. Lesser ranges can be provided through the use of energy absorbers.

C-2 Range modulation: Steps of 0.5 g/cm² over full depth Steps of 0.2 g/cm² for ranges < 5 g/cm²

The extent in depth of the constant dose region (defined as the width of spread-out Bragg Peak (SOBP), between the distal and proximal 90% points of the peak dose, see Appendix [D.1]) should be variable in steps of 0.5 g/cm² from a minimum of 0.5 g/cm² to the full range of the beam. (The practical limit is less than the full range of the beam where the dose in plateau becomes comparable to that in SOBP. See [4.1.4].) The greatest flexibility in dose delivery is achieved if this variation in range can be achieved by rapidly varying the energy of the beam extracted from the accelerator [2.1.2]. If mechanical beam modulating devices such as metallic or

⁵ K. P. Gall, L. Verhey, J. Alonso, J. Castro, J. M. Collier, W. Chu, I. Daftari, M. Goitein, H. Kubo, B. Ludewigt, J. Munzenrider, P. Petti, T. Renner, S. Rosenthal, A. Smith, J. Staples, H. Suit, and A. Thornton, "State of Art? New proton medical facilities for the Massachusetts General Hospital and the University of California Davis Medical Center," Nucl. Instrum. and Methods in Phys. Res., 1993, to be published.

plastic "range filters" or "propellers" are employed, the resulting step size for the range modulation may be practically limited to 1.0 g/cm^2 .

C-3 Range adjustment: Steps of 0.1 g/cm^2
Steps of 0.05 g/cm^2 for ranges $< 5 \text{ g/cm}^2$

The residual range of the beam in the patient should be adjustable in fine step sizes. This adjustment can be made either by varying the energy of the beam from the accelerator or by degrading the energy of the beam with absorbers, or by both techniques in tandem. To minimize neutron production and preserve beam quality (minimize emittance growth), it is most desirable that energy variation from the accelerator be used as much as possible and that absorbers be used only for fine-tuning the beam range. See [2.1.4].

C-4 Average dose rate: 1 Gy/min for $25 \text{ cm} \times 25 \text{ cm}$ field at a depth of 32 g/cm^2

The average dose rate in the target volume depends on the beam intensity entering patient, the volume of the target, the shape of the target, the beam spreading technique, the beam delivery system design, the transmission efficiency from accelerator to treatment room and the technique for energy variation. Overall efficiency of particle use can approach 50% for scattering systems, but might be significantly less for heavily collimated beams. The beam intensity required is that which is needed to treat the largest commonly used field sizes (approximately $25 \text{ cm} \times 25 \text{ cm}$) at the maximum required depth (32 g/cm^2) to a dose of 2 Gy in 2 min , with 2 Gy in 1 min is more desirable. For field sizes less than $5 \text{ cm} \times 5 \text{ cm}$, an average dose rate of at least 10 Gy in 1 min at a depth of 3 g/cm^2 is required. Providing margin in the accelerator and beam transport design to assure adequate dose rate is desirable. Note that if the lowest beam energy of 70 MeV is obtained by degrading from 250 MeV and then momentum analyzing the resulting beam, significantly higher extracted beam intensities would be required.

C-5 Time structure of the extracted beam: Suitable for beam scanning: "beam on" for more than 50% of time and number of protons in a "spike" $< 1 \times 10^6$

Although the instantaneous dose rate can be much larger than the average dose rate, it is mandatory to keep it low enough so that dosimetry and radiobiology are not adversely affected. Higher duty factors keep dosimetry simpler and more reliable and are therefore to be preferred. Since the ability to develop active beam

scanning is desirable, the spill structure, repetition rate, spill width, extracted beam intensity and position stability must be adequate to allow active beam scanning. Accelerators with very short ($\ll 1$ msec) beam pulses must run at a frequency > 400 Hz with a good (better than 10%) intensity control for every pulse. A feasible beam scanning implementation must be shown for accelerators with any proposed spill structure. See [2.2.2 ~ 2.2.7].

C-6 Field size:	Fixed-beam:	$> 40 \text{ cm} \times 40 \text{ cm}$
	Gantry beam:	$> 26 \text{ cm} \times 20 \text{ cm}$

It is recognized that the maximum field size (defined at isocenter) may impact significantly on facility cost, in particular for a gantry beam. Therefore different specifications are given for the fixed, horizontal beam line and the gantry. The largest fields ($> 25 \text{ cm} \times 25 \text{ cm}$) may (less desirably) be subject to some restrictions:

They may require active beam scanning.

Long-axis scanning may be performed by translating the patient.

The range in patient is nominal 32 g/cm^2 . With cost justifications, the range in patient may be reduced to 27 g/cm^2 .

Note: The maximum field size for the gantry is particularly sensitive to the technique for beam shaping (scattering or scanning), the distance from the effective source position to the patient and the size of the final magnet. Gantry designs with field sizes larger than specified, up to a field size of $40 \text{ cm} \times 30 \text{ cm}$, will be desirable.

C-7 Dose compliance:	$\pm 2.5 \%$ of the prescribed dose over treatment field
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We define the treatment field as $2\times$ penumbra widths (80% - 20%) inside the 50% point laterally, $2\times$ distal falloff widths (80% - 20%) inside the 50% point distally and 1 distal falloff width inside the 90% point proximally. The *dose compliance* is defined as the maximum dose variation from the specified dose within the treatment field. For purposes of this specification we will consider any field greater than $5 \text{ cm} \times 5 \text{ cm}$ with a SOBP of 5 cm or greater in water.

C-8 Effective SAD:	$> 3 \text{ m}$ (for gantry)
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The maximum dose to the patient surface relative to the dose in the SOBP increases as the effective source-to-axis distance (SAD) decreases. For a fixed, horizontal beam, large SAD's are easy to achieve; but not for gantry beam lines. A

smaller gantry with a physical outer diameter of less than 2 meters may have important cost implications. Such a gantry would require magnetic optics to ensure that the effective source-to-axis distance is large enough to provide adequate skin sparing. Note, that the 3 meter SAD should not be construed as a limit for the fixed, horizontal beam where greater distances can be inexpensively obtained and are highly desirable. See [3.4.2].

C-9 Distal dose falloff: 0.1 g/cm² above range straggling
(80% - 20%)

The physical limit of the distal dose falloff is determined by the inherent range straggling of a monoenergetic proton beam in the patient. Proton range straggling, defined as the standard deviation of the Gaussian of the stopping distribution, is approximately 1.1% of the proton range, so at 250 MeV it is about 4.5 mm, at 150 MeV, about 2 mm and at 100 MeV, about 1 mm. The 80%-20% falloff width, as measured along the central axis of the radiation field, is approximately 1.3 times the standard deviation of the Gaussian of the stopping distribution. The specification constrains the momentum spread of the beam to contribute no more than 1 mm to the total distal falloff width measured in a water phantom for a beam of any energy. This limits the accelerator/beam transport system choices to variable energy extraction (*e.g.*, synchrotron) and fixed-energy beam extraction (*e.g.*, cyclotron) followed by momentum selection.

C-10 Lateral penumbra: 2 mm over penumbra caused by multiple scattering
(80% - 20%)

It is generally desirable to have the steepest possible gradient in dose at the lateral edges of the beam. The lateral beam sharpness for a scattered beam depends mainly on the emittance of the beam at the entrance to the nozzle, plus emittance growth due to scatter in air, in beam degraders, at collimator edges in transit to the patient and the multiple scattering inside the patient. The preferred specification constrains the beam delivery design to contribute no more than 2 mm to the 80% - 20% lateral penumbra above that which occurs from the natural penumbra increase due to multiple scattering effects in the patient. For purposes of measurement, this penumbra will be determined in air, at isocenter, in the middle of a SOBP, with the beam-defining collimator located 20 cm upstream. Note that for very small fields (*e.g.*, < 5 cm diameter) used for treatments of tumors in the eye and brain, the penumbra at the surface is expected to be better than 2.0 mm.

C-11 Delivered dose accuracy: $\pm 2\%$

The absolute accuracy of the delivered dose should be better than $\pm 2\%$ of the specified dose.

1. Performance Specification for the General Facilities

1.1 Treatment Rooms

The proton medical facility will have two or three rotating gantry treatment rooms and one horizontal fixed-beam treatment room. If the construction proceeds in phased mode, at least one gantry room and one fixed-beam room must be provided in the initial phase. The initial facility must be constructed in such a way that it will be compatible with future expansion in a cost-effective manner.

1.1.1. The horizontal fixed-beam room: The horizontal fixed-beam room must be designed so that small-field treatments (*e.g.*, for eye treatment) and the large-field (up to 40 cm × 40 cm) treatments can be performed. The equipment switch time between the eye treatment and the large-field treatment must be <10 min.

One way to accomplish this requirement is the installation of ISAH (Isocentric Stereotactic Apparatus for Human, currently located in the Bevalac facility of the Lawrence Berkeley Laboratory) or a similar equipment in the horizontal fixed-beam room. ISAH will facilitate both small-field treatments and horizontal beam large-field treatments. The distance available for beam spreading must be sufficiently large, approximately 5 m, so that the large field size at the target, up to 40 cm × 40 cm, is obtainable.

1.1.2. The rotating gantry room: The rotating gantry room must be designed to provide 26 cm × 20 cm fields. Together with the couch specification [6.3.7], the facility must be able to irradiate any part of patient from any direction.

1.1.3. Beam orientations: Fixed for horizontal beam and 4π steradian for gantry beam.

A gantry rotating in a vertical plane, coupled with a movable patient couch (3 translations + rotation about vertical axis) can bring a beam into a supine patient from any angle, *i.e.*, full 4π steradian beam delivery around the patient.

1.1.4. The treatment-room associated ancillary facilities: For each treatment room, there must be a patient setup room, a patient equipment storage area, a treatment console area, etc.

These facilities have been specified in the Building Specifications Document of the facility, which describes the size and locations of rooms including such rooms as patient waiting, dressing rooms, and other facilities.

1.2. Facility Availability

1.2.1. Facility availability: The entire facility shall be available for treatment at least 95% of the scheduled facility-use time.

Reliability of individual components must be extremely high, maintenance procedures must stress early detection of weak components, and failures must be diagnosed and repaired quickly. Control systems should stress self-diagnosis of problems. The entire facility shall be available for treatment at least 95% of the time, that is, 95% of scheduled treatments will be given with a minor delay of no more than 5 minutes due to equipment malfunctions.

1.3. Treatment beams

1.3.1. Beam delivery systems: Passive (scattering [4.1]) or active (scanning [4.2]) beam delivery systems must be provided.

The choice of beam spreading system, both laterally and in depth, is an important element in the cost, complexity and flexibility of the facility. A scattering system, while substantially less expensive and less dependent on accelerator performance (with the exception of beam position stability), substantially limits flexibility in beam delivery and degrades lateral penumbra. Active magnetic beam deflection systems offer flexibility at the expense of increased dependence on spill structure and intensity control. It is envisioned that passive scattering will be used in the initial design, but the possibility of going to active scanning in the future must be part of the facility design.

1.4. Dosimetry reproducibility

1.4.1. Dosimetry reproducibility: $\pm 1.5\%$ (2 s.d.) for one day and
 $\pm 3.0\%$ (2 s.d.) for one week

Daily reproducibility of the dosimetry system must be within $\pm 1.5\%$ limits (2 s.d.) over the span of one day and $\pm 3.0\%$ (2 s.d.) over a period of at least one week.

Sufficient redundancy in dosimetry devices and measurements must be provided to ensure no loss of dosimetric information should any one device malfunction.

1.5. Control system

1.5.1. Treatment control system: The proton medical facility control system must control and/or interface to the accelerator, safety systems, beam lines, treatment rooms, dosimetry systems, patient positioners, and beam modifying devices. The system should permit pulse-to-pulse and within-a-pulse control of the accelerator, pulse-to-pulse monitoring of dosimetry, rapid beam switching and efficient facility startup and shutdown. See [Sec. 5].

The time and number of operations needed to operate all components of the facility should be minimized so that operators need only enter the minimum amount of information necessary to specify the desired state of the system. In general, the control system should permit the following operations to be performed in a timely manner (also see [2.4.2]):

1. startup at the start of the day from standby status in < 60 min.
2. startup from a cold start (with good vacuum) in < 120 min.
3. shutdown at the end of the day to standby status in < 15 min.
4. manual setup of all parameters needed for treatment in one room (excluding adjusting gantry angle and beam-modifying devices) in < 1 min.
5. automatic setup of all parameters (from a pre-stored table) needed for treatment in one room (excluding adjusting gantry angle and beam-modifying devices) in < 0.5 min.
6. time required to shut the beam off after a HALT (see [5.12.1]) is requested should be very short ($\sim 10 \mu\text{sec}$) and the time to restart treatment after a HALT should be < 2 sec.
7. time to terminate treatment ("soft" emergency off) must be the lesser of 1 sec or 0.2 Gy delivered dose.

1.6. Radiation safety of the facility

1.6.1. Radiation levels inside and outside facility: Shielding designs must appropriately protect personnel working in the facility (radiation workers) as well as non-radiation workers and visitors. Patient exposure outside the designated treatment fields should be kept within regulatory limits. Principles of ALARA must be applied.

There are certain equipment design features that do impact the shielding requirements. Design considerations of concern in this regard include: techniques that call for large beam losses in the accelerator or transport system (such as degraders associated with fixed-energy accelerators or emittance filters), low-efficiency beam spreading techniques (large beam losses on collimators in the treatment room), techniques that call for large amounts of material in the beam inside the treatment room (inefficient scattering systems, range degraders near the patient). Where such beam losses are planned, local shielding should be designed and radiation levels outside the local shielding estimated. Neutron levels are of concern, as well as long-term activation of components and shielding.

1.7. Operation costs

1.7.1. Low operation costs: Operating costs for the facility must be kept at the lowest possible level. The operating costs include the utility costs, maintenance costs (both personnel and parts), and operating personnel costs.

Radiation therapists will be expected to control the beam to each room with a radiation physicist on-site to handle special problems. A full-time accelerator physicist will be on-call at all times but should not have to be routinely present during facility operations. A full-time engineer and technician, dedicated to operations and maintenance of the technical components, should be adequate for normal operations.

2. Performance Specifications for Accelerator Systems

Introduction

The accelerator is specified as being scanning-ready. For economic and technical considerations, beam spreading by scattering will likely be used at the outset of operations, with the scattering system(s) later replaced by scanning systems. This replacement will proceed with minimal modifications of the accelerator itself, which will already be capable of operation in the beam scanning mode.

For scattering mode treatment, some of the operating parameters for the accelerator will not be as tight, as is pointed out below, but these relaxed parameters are not to be viewed as a reduction in the requirements for the accelerator: the required specifications are the scanning-ready ones.

In the upgrade of the rest of the facility downstream of the accelerator from scattering to scanning, some parameters, such as emittance, both from the accelerator, and delivered to the gantry after having traversed the beam monitors, will not change significantly. The emittance requirements for small beam at the isocenter for scanning operation will also be required to minimize the aperture requirement of the magnets in the gantry in both scattering and scanning operation. Other parameters, such as the time-dependent intensity variation of the beam, may play a less important role in beam scattering operation, but will still be required as part of the scanning-ready specification.

The accelerator parameters are divided into three general categories: energy, intensity and quality. The discussions on the implication of beam scanning on the design of facility is appended in Sec. D.

Accelerator Performance Specifications

2.1. Energy

2.1.1. Energy Range: 70-250 MeV protons at the gantry exit measured with the beam monitors used during patient treatments, but before the vacuum exit window.⁶

Based on the range in the patient and the total amount of absorbing materials in the beam line such as monitors and windows, the energy of extracted protons will be continually variable over the limits of 70 to 250 MeV at the exit of the gantry.

The actual stopping range in the patient will depend on the nature of the beam spreading process, scanning vs. scattering, and how much material such as scatterers and monitors downstream of the gantry exit are present in the beam. The upper energy corresponds to a proton range of 38 cm in water, and may be reduced by minimizing the material in the beam line as long as the range of the 32-cm beam in patient [C-1] is satisfied.

2.1.2. Time to Establish a New Extraction Energy: Next pulse or one second.

The treatment process may require that several stepped energies be available during a treatment. The maximum treatment time is two minutes, and as many as 30 different energies may be required during a given treatment. For a synchrotron with a nominal cycle time of two seconds, taking even one pulse away from treatment for each energy to verify the new extraction conditions would add 60 seconds to the treatment, an unacceptable lowering of efficiency. Therefore, the newly selected extracted beam energy must be available on the first pulse at that energy. A method must be provided to verify that the correct energy has been provided, such as independent control of the beam transport system magnets with a design that has a reasonably small momentum aperture. See [3.3.3].

2.1.3. Energy Precision: The energy will be within ± 0.4 MeV of the requested energy over the entire range.

The actual extraction energy of the machine must be accurate to within ± 0.4 MeV to satisfy the depth accuracy of the Bragg peak. See [C-2] and [C-3].

⁶ The accelerator vacuum will be maintained throughout the beam transport system up to the point where it interfaces with the treatment beam line. For the gantry beam line, the vacuum exit window is located at the exit of the last bending magnet in the gantry. See [3.1.5].

2.1.4. Energy Variability: The resolution of the energy-determining system will be no greater than ± 0.4 MeV over the entire range.

The fineness of the energy variation affects the residual range of the beam in the patient. The range adjustment, obtained by varying the energy of the beam, must allow steps of 0.1 g/cm^2 , or 0.05 g/cm^2 for ranges less than 5 g/cm^2 [C-3]. The beam energy may be determined by assuming the beam stops in water and applying the usual range formulas for protons. A 0.4-MeV resolution over the entire range will satisfy the range adjustment requirement.

2.1.5. Energy Spread: $\leq \pm 0.1\%$ FWHM at exit of gantry at 100 MeV and up, measured with the beam monitors used during patient treatments, but before the vacuum window.

This requirement is driven mainly by the momentum aperture of the beam transport system and gantry, although the diffuseness of the fall-off of the distal peak [C-9] will also limit the acceptable energy spread.

2.1.6. Energy Variations of Extraction: $\leq \pm 0.1\%$

The energy dependence of the accelerator extraction system may cause a variation in the energy centroid during the extraction period if not carefully designed. The variation of the average energy of the beam during the spill or from spill to spill must not vary by more than $\pm 0.1\%$.

The large dispersion function in small, weak-focusing synchrotrons significantly widens the beam in the vacuum chamber and may promote a strong energy dependence of the extraction process. This energy dependence may cause a sweep of the mean beam energy for the duration of a spill. The use of r.f.-on spill may alleviate this problem and may also result in a lower energy spread of the extracted beam.

2.2. Beam Intensity

The term *beam intensity* is used by accelerator physicists and medical physicists to mean quite different things, and we wish to clarify its use in this document.

The rigorous definitions of terms involving the number of accelerated particles are as follows:

Number of particles, N

Fluence, Φ : particles/unit area, $\Phi = dN/da$

Flux, F : particles/unit time, $F = dN/dt$

Intensity, I : energy/unit area/unit time,

$$I = E d^2N/dt da = E d\Phi/dt = E dF/da, \quad (\text{def. 1})$$

where E is the energy of the particles.

For our purpose of describing mono-energetic particles, it is convenient to define:

Intensity, I : particles/unit area/unit time,

$$I = d^2N/dt da = d\Phi/dt = dF/da. \quad (\text{def. 2})$$

Accelerator physicists, however, uses the term *beam intensity* to mean the number of particles per unit time, i.e., the same as the *flux* defined above.

Intensity, I : particles/unit time,

$$I = dN/dt = F, \quad (\text{def. 3})$$

and $qe \cdot I = qe dN/dt = \text{beam current}$.

With this definition, the beam intensity does not vary when the beam cross-section changes. Also the *beam intensity* modulation means the *beam flux* modulation. In this document, we will use the *beam intensity* to mean always *particles per unit time* (def. 3). For protons $qe = +1$, and the *beam intensity* and *beam current* are used interchangeably.

In the literature, to describe the process of obtaining uniform dose distributions by accumulating raster-scanned beam spots with Gaussian-like *intensity* distribution, the term *intensity* is used to mean $d^2N/dt da$ (def. 2). To further confuse the issue, in the description of voxel scanning the term *intensity* is often used to mean dN/da , which is the *fluence*.

To avoid confusion, we have used in this document the term *beam intensity* to mean only dN/dt (def. 3), and avoided using it in other meanings.

2.2.1. Beam intensity (dN/dt): 10^{11} /second at 200 MeV, averaged over one cycle at end of gantry, including all losses in the transport system with the usual monitors required to be in the beam used during patient treatment, measured upstream of the vacuum exit window in the gantry.

The average intensity at the vacuum exit window will be a minimum of 10^{11} protons/second averaged over one cycle, or 2×10^{11} protons/spill for a 1/2 Hz synchrotron at 200 MeV averaged over one cycle of the accelerator.

Clinical specifications [C-4] calls for a dose of 2 Gy in a 25 cm $\times$ 25 cm field in 2 minutes. For a 2 Gy dose, about 5×10^{11} protons must be delivered to the most distal layer. The number of protons required is a factor two to six less for the other layers. With the specified beam intensity the required dose can be given in three beam pulses to the most distal layers and in two or less spills to all others. If the target volume is scanned (in all three dimensions) several times during the course of the treatment, fewer protons are delivered in one scan, and the required dose can be given to each layer in one pulse.

If a scattering system is employed, about 1.8×10^{12} protons must be delivered within the specified field. Assuming a beam use efficiency of 20%, about 90 seconds are needed for the treatment at the specified maximum intensity. This time is within the clinical specifications.

2.2.2. Spill Length: 1.0 second minimum. Extended flat-tops are desirable with corresponding less current (dN/dt) acceptable corresponding to the same circulating current in the synchrotron as for the 1 second spill. Variable spill lengths down to 0.1 second are also acceptable if the synchrotron cycle rate can be correspondingly increased.

This time allows a raster scan of the entire field within one spill even for the largest fields of 40 cm $\times$ 40 cm. A voxel scanning system could be operated with shorter spills since there is no need for covering the entire field in one spill.

A spill length of 100 msec is sufficient for a scattering system.

Variable spill length down to 0.1 second is desirable if the cycle rate can be correspondingly increased, increasing the average intensity. For example, a synchrotron with a 1 second flat-top and a 1 second ramp-down, reset and ramp up with a 2 second cycle may operate with a 1.1 second cycle with a 0.1 second flat-top. With the same accelerator change, the average intensity is 82% higher. This mode may be useful in scattering mode where the beam use efficiency is lower than for scanning, and where beam time structure is less critical.

2.2.3. Macroscopic (Spill to Total Cycle Time) Duty Factor: Fraction of machine cycle in which beam is available: $\geq 50\%$

Beam scanning and accurate beam intensity monitoring requires the highest duty factor possible to reduce the slew rate requirements of the scanning magnets and to minimize saturation effects in the beam monitors.

A 10% duty factor is sufficient for a scattering system to avoid saturation effects in beam monitors and dosimeters, as provided in [2.2.2].

2.2.4. Microscopic (r.f.) Duty Factor: Full modulation by r.f. in the MHz range is acceptable.

Proton synchrotrons and cyclotrons produce a tightly bunched beam with a microstructure frequency of several MHz. Proton beams with r.f. structure are currently in use at LLUMC and at the Harvard Cyclotron, and the radiobiological response in tissue has been measured. The beam may be fully modulated by r.f. in the MHz range if it eases the design of the accelerator extraction system.

2.2.5. Undesired Beam Intensity Modulation: Acceptable time structures in extracted beam are specified below for scanning and scattering modes.

The raster scanning system may use variable scan velocity modulation to vary the dose over the treatment volume. The scanning system will sense instantaneous beam intensity and, along with required dose per voxel, will calculate the raster speed. The instantaneous beam intensity from the accelerator, in the most basic configuration, need not have an intensity modulation capability, but the undesired modulation of the beam must be held within certain limits described below. This will require fast feedback systems measuring the instantaneous beam intensity and correcting the extraction system parameters.

It will be desirable to provide, as an upgrade, variable intensity extraction, which is described in the next section.

The modulation of the extracted beam is specified as a function of a windowing time. Faster variations are more permissible, as the finite size of the pencil beam integrates over the spatial variations of the dose. Slower variations are corrected by varying the sweep rate of the variable velocity sweep of the raster scanner. The limits of the sweep speed of the scanner, and the saturation effects in the beam monitors impose a maximum instantaneous extraction rate.

The limit on intensity excursions are given as a function of a time window in which the beam is integrated and compared to the average spill rate. For longer time windows specified in the table below, the integrated beam variation must be

less than $\pm 20\%$ in any time window, relaxing to larger variations permitted in shorter time windows.

Ideally, one wants a d.c. beam with the instantaneous beam current within $\pm 2\%$ of its average value during the spill. If a constant beam current were guaranteed, the modulation of the scan speed for shaping and optimizing the dose distribution could be calculated before the irradiation and performed without a feedback loop. For time intervals shorter than 25 μsec a rapidly varying time structure is irrelevant since the beam spot will move less than 1 mm during that time at the highest scan speed.

The scanning system specifications which use a variable scan speed, controlled to $\pm 2\%$ averaged over time intervals longer than 100 μsecond and to $\pm 20\%$ when averaged over 25 μsec to 100 μsec . By measuring the current of the scanned beam's intensity fluctuations the dose may be controlled by varying the scan speed accordingly. The lower the undesired beam intensity fluctuations are, the easier it is to achieve the specified accuracy in the dose deposition. The undesired spill structure as specified in the table is believed to be an achievable compromise.

The limits of the intensity excursion, or peak intensity, integrated within the specified window time for the instantaneous extracted beam rate are specified as follows:

Scanning Method Requirements

Window Time	Maximum Excursion
> 200 μsec	$\pm 20\%$
200 μsec – 100 μsec	Linearly rising to $\pm 100\%$ at 100 μsec
100 μsec –25 μsec	Linearly rising to excursions $5\times$ average spill rate, or less than 5×10^6 particles, whichever is more at 25 μsec .
<25 μsec	No specification — will be controlled by the r.f. structure.

Scattering Method Requirements

Window Time	Maximum Excursion
1 millisecond	No more than 10^9 protons, or 0.1% of the total number of protons in the treatment, whichever is less.

No time interval of 25 μ sec may contain more than five times the average number of protons, or 5×10^6 protons, whichever is more, since neither the scanning system nor the beam abort [5.12.3] can reliably react in less than 25 μ sec. The estimate for the tolerable number of protons is based on the assumption that if all the particles are deposited in one spot, it will not result in more than a 10% overdose in that spot for that particular scan.

If a scattering system is used, the spill structure has no impact unless it prevents an accurate cutoff at the end of the treatment, or spikes in the spill which lead to dosimeter saturation. No one millisecond interval may contain more than 10^9 protons or 0.1% of the total number of protons for the treatment, whichever is less.

2.2.6. Beam Intensity Modulation Capability Within Pulse: Minimum implementation: no modulation needed — variable velocity scanning used. Upgrade path: 100:1 dynamic range down from rate that produces maximum intensity, with bandwidth from d.c. to 5 kHz.

The minimum modulation requirement is that there be no modulation capability. The dose variations over the tumor volume will be provided entirely by velocity modulation of the scanned beam. The ripple requirements specified in [2.2.5] above apply.

A more desirable capability, obtained by providing an upgrade path to the modulation capability, will be to modulate the beam intensity extracted from the accelerator over a range of 100:1 with a frequency range of d.c. to 5 kHz. A modulation capability within a beam pulse would enhance the capability of the scanning system to deliver specified dose distributions. The modulation capability would be nominally downward from maximum intensity, but with the ability to keep the feedback loops closed at the minimum intensity. The 100:1 range can include, if possible, some upward modulation in its range, such as a factor of 3 upward, and 30 downward over normal spill, for example. This modulation capability would extend over the range of 10^9 to 10^{11} protons/second peak, so the lowest controlled rate would be 10^7 protons/second at the lowest rate at the lowest peak intensity.

A modulation capability would not be useful with scattering treatment delivery systems.

2.2.7. Pulse-to-Pulse Selection of Beam Intensity: 1000:1 variation of circulating beam intensity from pulse-to-pulse specified by data arriving no less than 0.1 second before injection with $\pm 10\%$ accuracy at the 10^8 /second average intensity level, increasing in accuracy to $\pm 2\%$ at the 10^{11} /sec average intensity level.

The circulating beam intensity in the synchrotron must be variable over a 1000:1 dynamic range on a pulse-to-pulse basis with a $\pm 10\%$ accuracy at the 10^8 protons/second spill level, increasing to $\pm 2\%$ accuracy at the 10^{11} /sec average intensity level. This provides the basis for setting the extraction parameters for the next extracted pulse, for example, for the last "filling in" pulse which finishes the current longitudinal plane in the treatment volume. It will permit lower level exposures of diagnostic x-ray film for alignment verification.

If a scattering system is employed it will permit starting the treatment at a low intensity and to correct the beam centering at that intensity level before irradiating with full intensity.

Data will be provided to the accelerator control system of the required circulating beam intensity at extraction, no later than 0.1 second before the next linac injection pulse.

Various methods can be applied to reduce the circulating intensity, such as temporarily reducing the r.f. bucket size during acceleration, or by reducing the length of the injected beam pulse.

2.2.8. Beam ABORT Time: ≤ 10 μ seconds to completely shut off beam after a trigger signal is received.

The beam issuing from the synchrotron must cease within 10 μ seconds after receipt of a trigger signal. This corresponds to approximately 100 turns of the circulating beam in the synchrotron ring.

This is an important safety parameter when using a scanning system. At full beam intensity, about 2.5×10^6 protons are delivered into an approximately 1 cm^2 spot area within 25 μ sec, corresponding to about 0.5 cGy. If the beam current during that time were $100\times$ the average maximum value, a treatment could still be safely aborted. At most, a small spot would have received an unwanted dose of 5 cGy.

A beam abort time of 1 msec is sufficient for a scattering system since the beam is spread over a much larger area.

2.3. Quality of Extracted Beam

2.3.1. Transverse Emittance: $\leq 0.5\pi$ cm-mrad, rms, unnormalized, at 200 MeV, at accelerator exit.

The transverse emittance of the beam determines the size of the magnets in the beam transport system, which is of particular interest in the gantry, where weight must be minimized, and in determining the size of the beam spot at the isocenter.

The beam emittance from the accelerator is determined by the nature of the extraction process in the extraction plane, and largely by the adiabatic damping of the beam from injection in the perpendicular plane. As the synchrotron is likely to use single-turn injection, or at most a small number of turns, the circulating emittances in both planes are likely to be similar, and transverse coupling mechanisms would not be of particular concern. However, the betatron tunes in both planes must carefully avoid skirting or crossing sum resonances.

The out-of-extraction-plane emittance is determined by the linac emittance and for an ideal synchrotron the normalized emittance remains constant. Various mechanisms increase it somewhat. The in-plane extracted emittance is determined by the nature of the resonant extraction system, but in practice the emittances of the extracted beam in the two transverse planes are usually somewhat similar. The unnormalized rms emittance of the beam extracted from the synchrotron would normally fall in the $0.2 - 0.5\pi$ cm-mrad range.

2.3.2. Position and Angle Stability of extracted beam: Extracted beam, measured at synchrotron exit, must not vary by more than ± 1 mm or by ± 1 mrad during the pulse, or between pulses at the same energy. See [Sec. 3].

The variations in position and angle of the extracted beam must not cause position and size variations of the beam at the isocenter by more than 10% of the rms beam size at the isocenter either during a single pulse or from pulse to pulse at constant energy. To satisfy this, the position and angle of the transverse beam centroids exiting from the accelerator must not vary by more than ± 1 mm, or by ± 1 mrad during an entire spill cycle.

2.4. Accelerator Beam Monitoring

2.4.1. Monitoring of Beam Circulating in Synchrotron: Primary beam monitor must operate down to 5×10^6 circulating protons with an accuracy no worse than $\pm 10\%$, improving in accuracy to no worse than $\pm 2\%$ at 10^8 or more circulating protons.

The dynamic range and accuracy of the circulating beam monitor ensures safety and accuracy of the applied dose. The patient treatment system requires an accurate measurement of the available proton intensity for each spill to prepare the scanning for that spill.

In addition, it is desirable to measure the beam centroid position in each straight section of the accelerator for closed orbit measurement and control, for tune measurements, and for other diagnostic purposes.

The usual single-turn monitors will be provided for initial tune-up and injection studies.

2.4.2. Time to recover from various shut-down conditions: Time to start up or shut down from various conditions are specified in the table below.

Item	Startup/Shutdown Time
Facility startup from total shutdown	1 Day
Daily operation startup to point where dosimetry can be done	1 hour
Control system startup so start and check computer	30 minutes
Daily operation shutdown time to safe mode	15 minutes
Facility shutdown and secure time	4 hours

For related specifications, see [1.5.1]

3. Performance Specifications for Beam Transport Systems

Introduction

The beam transport system brings the beam from the accelerator into the treatment room, and includes monitoring and safety functions. The rotating gantry is included as a part of the beam transport system. All parameters are for a treatment room with a gantry unless otherwise specified. The treatment beam line (nozzle) is discussed in [Sec. 4].

The specifications of the beam transport system are based on requirements of the dose shaping (nozzle or beam delivery) system. The nozzle design [Sec. 4] determines the limits of the parameters of the beam transmitted through it.

The nozzle comprises the devices which laterally spread the beam, modulate the range of the particles, monitor the beam, and perform dosimetric and safety functions. The lateral and transverse spreading of the proton beams can be done in a variety of ways ranging from purely passive methods using scattering foils and range shifting devices to actively scanning a narrow pencil beam laterally and in depth. See [Sec. 4].

The dose shaping system which requires the highest performance of the accelerator and beam transport system is the three-dimensional scanning system which uses a narrow pencil beam to scan the treatment volume with the Bragg-ionization peak transversely and in depth [Sec. 4]. Because the accelerator and beam transport system specifications are ultimately driven by the requirements of the scanning system, the accelerator and beam transport system are specified as "scanning ready", *i.e.*, it will transport the beam from the accelerator to the nozzle as required by a pencil beam scanning system. The accelerator and beam transport system of a new proton therapy facility should be able to provide the appropriate beams for 3-D scanning whether the beam scanning is implemented from the start or not.

Beam Transport System Description and Requirements

The general requirements of the beam transport system for the radiotherapy facility are described. Features unique to this application will be emphasized. The section under Modular Design heading below is not a specification document but guidelines to the design of the beam transport system.

The design of any beam transport system reflects the artistry of the designer more than that of any other accelerator-related system. There is a wide spectrum of choices, any of which would satisfy the overall requirements of the beam transport system. We will outline the general configuration and requirements of the transport system, but the detailed design will be left to the vendor.

To help guide the transport system designer, a strawman design example is given in the Appendix 2. This design includes all elements normally found in a biomedical beam transport system and serves to illustrate many of the requirements peculiar to this application. The design is broken down into seven modules, not including the nozzle optics. This design is for illustration purpose only and is not part of specification. The following discussion relates to the design example.

Modular Design of Beam Transport System

A modular design breaks the transport system into several sections which can be analyzed somewhat independently of each other. In addition, a modular system allows easy extension or duplication of subcomponents, such as multiple gantries, each with the same beam optics, but tapped off at different distances away from the accelerator. If each module, for example, is rendered achromatic, then the beam in other parts of the system will have no chromatic dispersion, which simplifies the design, tuning and monitoring.

This beam transport system lends itself to modularization into seven subsystems, each of which can be developed and analyzed separately. Each has a unique function, and its tuning can proceed independently of those modules downstream, simplifying and reducing the interdependencies of various systems.

The seven subsystems are:

- (1) **Initial vertical deflection elements and beam dump system.** The beam exits the accelerator vertically downward toward a beam dump in the floor. The beam is bent back up to the required height from the floor, and then rendered horizontal by a system of magnets, achromatically if possible. The initial beam properties (centroid, angle, etc.) may be monitored at this point.
- (2) **Initial match into periodic transport system.** The beam will be transported along a backbone by a periodic transport system (see next item). The beam

must be matched into this periodic system by a focusing section with enough range to accommodate the variations in beam parameters from the accelerator.

- (3) **Periodic transport lattice.** The beam will be transported to a number of tap-off points by the periodic transport system. At every multiple of π phase advance along this system, the beam envelop parameters are reproduced. At these points, beam may be tapped off for each treatment nozzle, allowing each beam delivery system to have the same optics.

The periodic transport lattice may also be used for beam clean-up and emittance control. Collimators every 90° or 60° phase advance, for example, can be used to establish the emittance of the beam, equalizing both planes for compatibility with the round beam requirement at the gantry rotation point.

- (4) **Achromatic tap-off points.** The beam along the periodic transport lattice is bent toward each gantry and fixed beam room by an achromatic tap-off, or allowed to proceed to a downstream user. Achromatism is required to relax the power supply regulation for the dipoles necessary to achieve required beam position stability for fast energy changes.
- (5) **Round beam generator.** At the gantry rotation point, the beam parameters in both transverse planes must be identical to avoid retuning when the gantry angle is changed. This requires an achromatic beam with identical emittances and betatron amplitude functions in both transverse planes.
- (6) **Gantry input matcher.** The round beam must then be matched into the optics of the gantry itself. The gantry consists of several large-bending-angle dipoles, which themselves focus the beam strongly. Quadrupoles will be included in the gantry to focus and achromatize the beam. The beam parameters at the first gantry dipole will likely be quite different in the two planes, which are accommodated by the input matcher.
- (7) **Achromatic gantry optics.** A corkscrew design is assumed. The long distance between the last gantry element and the isocenter, the achromaticity requirement and the range of beam spot size at the isocenter will require a large focusing range. The gantry optics must be achromatic for the same reason as for the tap-off optics. The size of the gantry magnets is strongly dependent on the emittance of the entering beam.
- (8) **Nozzle optics.** These include the scanning magnets, and will be treated in [Sec. 4].

The design of each module is somewhat decoupled, which allows a team approach, and provides easy expandability. The design of the transport section to the fixed-beam room will be less complex, and is not further discussed here.

Beam Transport Performance Specifications

3.1 Beam Energy

3.1.1. Beam energies and transmission: The transport system must be able to handle beam energies from 70 MeV to 250 MeV.

Proton beam energies:

- into the fixed-beam treatment room: 70 MeV – 250 MeV
- into the gantry treatment room: 100 MeV – 250 MeV

The transport system guides the beam to the tap-off points, where the beam is sent to the gantry or fixed beam room. The transfer matrix between these tap-off points is unity, so the beam parameters are identical at each tap-off point. This will allow identical optics in each beam delivery system. To ease the power supply regulation requirements and help insure a stable beam when changing energy, all bends should be fully achromatic.

3.1.2. Transmission efficiency and beam size: The transmission efficiency through the transport system should be maximized to lower the peak intensity (dN/dt) requirement of the synchrotron itself and reduce activation and secondary particle production along the beam line.

If the emittances of the beam are significantly different in the two transverse planes, they may need to be equalized for use in the gantry. The emittance of the beam emerging from the accelerator must be measured, and collimators may be inserted at proper places to shave the beam. This will create beam loss and secondary particle production, which must be taken into account in the accelerator intensity specification.

The aperture must clear the beam by a sufficient amount: 4 times the rms width of the beam is suggested for the diameter of the aperture in the transport system to allow good transmission, even with some alignment error. A smaller aperture may be necessary in the gantry beam line to reduce the weight and cost.

The actual transmission efficiency is not specified. The accelerator and beam transport together must satisfy the intensity requirement in [2.2.1] at the isocenter.

3.1.3. Beam dump: A beam dump must be provided near the accelerator for tune-up when required.

A beam dump in the floor, in-line with the original downward extraction trajectory, as used by the Loma Linda University Proton Facility, is a good solution. The fast beam-abort system (10 μ sec) could be placed here. See [2.2.8].

3.1.4. Instrumentation of the transport lines and the beam dump: The beam dump and the transport line to the beam dump must be sufficiently instrumented, including radiation monitors, to debug and develop accelerator and extraction system.

3.1.5. Continuous vacuum from accelerator to last window: All material in the beam line must be minimized to preserve the beam emittance.

At the gantry entrance a suitable rotating vacuum seal, such as a ferrofluidic seal, allows a continuous vacuum with no material in the beam up to the exit of the last bending magnet in the gantry.

3.2. Beam Parameters

3.2.1. Emittance at Gantry Exit: $\leq 1.0\pi$ cm-mrad, rms, unnormalized, at 200 MeV, measured with the beam monitors used during patient treatments, and before the vacuum window.

The transverse emittance at the end of the beam transfer line is determined by the materials present in the beam such as monitors, absorbers and gas.

The drift length between the last element in the gantry and the isocenter is approximately 3–3.4 meters. The rms beam spot size at the isocenter (measured in air, *i.e.*, without a patient in position) is ideally 3 mm with a divergence of less than 5 mrad. Thus, the beam at the exit of the last magnetic element in the gantry is highly constrained.

Proton scattering by material in the beam line can be significant. With the usual beam position monitors, dose monitors and vacuum windows in place for patient treatment, the unnormalized rms emittance could easily attain a value of $2\text{--}5\pi$ cm-mrad at the lower end of the energy range, which results in an unacceptably large spot at isocenter, or unacceptably large beam sizes in the gantry.

To deliver a spot of acceptable size, the amount of monitors in the beam must be minimized. For patient safety, the vacuum exit window may have to be located some distance away from the isocenter. As air scattering is significant at low energy, a helium bag may be required between the exit window and the patient to achieve the required beam size at isocenter.

The minimum transverse emittance requirement for the beam exiting the synchrotron is 0.5π cm-mrad, rms unnormalized at 200 MeV. A lower emittance is probably not worth the extra effort, as any monitoring device in the beam will immediately increase the emittance significantly.

3.2.2. Beam parameters at the isocenter in treatment room: The beam characteristics must be within the specifications listed in the table below for proton beam energies between 150 and 250 MeV.

Beam specifications at the isocenter:

Description	Specifications
Spot size	$\sigma_x, \sigma_y < 3$ mm
Spot deviation from circle	$ \Delta\sigma_x - \Delta\sigma_y < 0.3 \sigma_x$
Divergence	$\sigma'_x, \sigma'_y < 1/200$ radian
Spot position accuracy	$\Delta x, \Delta y < 1$ mm
Angular accuracy (maximum allowable deviation of actual beam central axis from nominal axis)	$< 0.2^\circ$

The beam parameters are defined *at isocenter* with the assumption of having the beam line vacuum extended all the way to isocenter and no scattering material, *i.e.*, beam monitors, dosimeters, etc., in the nozzle. Beam monitors, such as a detector for extraction feedback which must be in the beam during patient treatments, have to be in the beam when establishing the beam parameters listed below. In this way the beam is specified independently of the gantry angle, in particular the drift distance from the exit of the last magnet to isocenter. The specifications must be met for beam energies between 150 and 250 MeV.

3.2.3. Beam parameters at the gantry entrance: At the rotation point of the gantry entrance, the transport system must provide a round beam with identical emittance and betatron functions in both planes.

This is to prevent emittance dilution and eliminate retuning when the gantry angle is changed.

3.3. Beam Switching and Tuning:

3.3.1. Transport Line Tracking: The entire transport system through the gantry as well as the scanning system must track the pulse-to-pulse energy variation of the synchrotron.

Monitoring in the beam line for scanning must necessarily be minimal to keep the material present in the beam to a minimum to minimize emittance blow-up. Strong emphasis must be placed on system stability and reproducibility so that previously recorded beam transport set-ups can be reliably reproduced on a pulse-to-pulse basis.

3.3.2. Time to tune beam between treatment rooms: The beam switching time from one treatment room to another must take <1 minute.

Beam at the correct energy must be available for treatment in a new room no more than one minute after treatment is completed in another room. In addition to requiring that the new parameters for the accelerator and beam transport system be rapidly called up and established, the accuracy of beam position in the new room must be suitable to ensure meeting the field uniformity specification.

3.3.3. Beam-energy change during a treatment: For beam-energy change, the next beam energy must be available on the next synchrotron pulse. See [2.1.2].

For variable modulation treatments performed either with a scanning or a scattering system the beam energy will be changed up to 30 times during a given treatment. To keep the treatment time within clinical specifications, the next beam energy must be available on the next synchrotron pulse. In general, the beam energy must be changed in less than one second.

Energy stacking cannot be used easily with a scattering system, since the scatterer construction is energy-dependent. For a fixed energy accelerator, range spreading will be done almost continuously by means of ridge filters or propellers. The addition of this material in the beam may degrade the penumbra and increase neutron background in the treatment room.

3.3.4. Automatic beam tuning: After the initial daily setup and calibration *no* manual tuning or beam centering at the isocenter should be necessary when switching treatment rooms or changing the beam energy or gantry angle.

It should be possible to check the tune of the beam transport system up to the gantry entrance beam stop.

Automatic beam steering must ensure adequate centering to minimize beam loss along the transport system and compliance of the beam centroid and angle specifications at the gantry exit. The beam monitoring [3.2.2, 4.1.2] and beam abort [2.2.8, 3.5.2, 3.5.3] conditions apply for automatic beam tuning. As no manual tuning is possible with the patient in place, any feedback system that centers the beam must operate very quickly and at low intensity.

The entire beam transport system must track the accelerator pulse-to-pulse energy variation without retuning or test beams. This implies that the magnets may require field sensors.

For any gantry design the reproducibility and stability of the beam tune require achromatic beam optics.

3.4. Gantry:

3.4.1. Physical specifications of gantry: The gantry must accommodate a scattering as well as a scanning system. Its performance must meet the specifications listed below.

Description	Specifications
Size (diameter)	< 13 m
Rotation range	$\pm 185^\circ$ (overlap at the bottom)
Rotation accuracy	$\pm 0.3^\circ$
Rotation step size	$\pm 0.3^\circ$
Rotation speed	1 min for full rotation (see [3.5.6])
Braking	1° to complete stop (see [3.5.6])

In order to minimize treatment preparation time, the gantry rotation speed should be not less than 1 full revolution per minute. See [5.2.6].

3.4.2. Drift space in the gantry: The source-to-isocenter distance for a scattering system or the equivalent distance for a scanning system must be larger than 3 m.

A 3-meter drift distance from the last bending magnet to isocenter can accommodate either a scattering or a scanning system. However, compact gantries, such as the PSI (Paul Scherrer Institut, Villigen, Switzerland) design, with a shorter drift space which incorporate a scanning system have been designed.⁷ It should be noted that for a compact gantry to be considered it must accommodate a scattering system. This may require an innovative, and completely new design to achieve a field size required by the clinical specification [C-6].

The source-to-isocenter distance for a scattering system or the equivalent distance for a scanning system must be larger than 3 m to minimize the surface skin dose. If the divergence is not equal in all transverse directions as is the case for some scanning system designs, the mean value must be smaller than the corresponding value for a source-to-isocenter distance of 3 m.

3.4.3. Conformation of gantry rotation center to isocenter: The mechanical stability of the gantry under rotation must maintain the crossing points of the central beam axes within a 1 mm diameter sphere.

3.5. Beam Diagnostics, Monitoring, and Safety:

3.5.1. Beam Diagnostics and monitors in Beam Transport System: Diagnostic elements for facilitating a fast and straightforward beam tuning procedure must be provided throughout the beam transport system. Parameters to be measured at one or more points are the beam intensity, the beam centroid, the beam profile, and the emittance. The details of the required monitoring are listed in the table below. Also indicated in the table is the need for floating jaws.

Monitors must also be provided to verify the proper workings of systems, such as vacuum, radiation, temperature, and other systems.

⁷ Y. Jongen, W. Beeckman and A. Laisne, "Development of a low-cost compact cyclotron system for proton therapy," *Proc. of the NIRS International Workshop on Heavy Charged Particle Therapy and Related Subjects* (ed. by A. Itano and T. Kanai), July 1991, Chiba, Japan, 189-200 (1991).

Locations of required beam monitors and floating jaws.

Location	Intensity	Centroid	Profile	Emittance	Jaws
Accelerator exit	√	√	√	√	
Exit of initial matcher		√			
$n\pi$ points along spine		√			
Collimators along spine	√	√	√		√
Max. dispersion points		√			√
Gantry rotation points		√		√	
Gantry exit (part of nozzle)	√	√	√		
Beam stop exit	√				
Beam dump	√	√	√		

The energy aperture of the beam line is likely to be fairly small due to the large dispersion at some points, and the energy measurement may be monitoring the beam centroid at the high dispersion points.

The beam emittance growth must be minimized. Non-destructive monitors that are active all the time are preferred. They will enable auto-tuning as well as beam monitoring during treatments. Otherwise, beam monitors are required which introduce a minimum amount of material into the beam during tuning and can be withdrawn from the beam line during treatment. As the monitors will be frequently used, the mechanical insertion system must be designed for long lifetime (welded stainless vacuum bellows, for example).

3.5.2. Materials in the beam line: The material in the beam line due to monitors must be minimized.

The intensity, emittance and energy spread depend on the extracted energy. Monitors that place material in the beam increase the bare machine emittance and affect the beam spot size. The effect of every monitor in the beam line must be evaluated in terms of their accumulated effect on the total phase space at the isocenter and the ability to achieve the required beam-spot size.

This will be a formidable requirement: low energy protons scatter significantly in the thin ionization chambers usually used for this application. The ionization chambers provide an absolute intensity measurement and can be traced to calibration standards. In addition to intensity information, sufficient beam position, size and energy information must be obtained to ensure the safety and efficacy of

the treatment, especially if the energy is varied on a pulse-to-pulse basis. Once the patient is in place, tuning the beam at full intensity all the way to the isocenter is no longer feasible.

Even if the beam is spread by scattering, the emittance of the beam presented to the gantry is important to insure that the beam will pass through the magnets. The cost of the gantry is strongly dependent on the aperture of the magnets, which impacts the suspended weight and power requirements. Although the accelerator is specified as scanning-ready from the outset, economics may dictate that scattering is used initially.

3.5.2. Beam Halt / Abort: Beam halt/abort time after detecting a crash condition: time to clamp the beam $< 10 \mu\text{sec}$; time to insert beam plug $< 5 \text{ sec}$.

Several layers of patient protection must be provided by beam stops and treatment aborts. The most important safety feature is the ability to switch the beam off in less than $10 \mu\text{sec}$ after an error condition has been detected. (See [5.1.2] for definitions of terms, halt, abort, clamp and cutoff.) This capability may be achieved by a fast deflector implemented in a "fail-safe" manner. For example, a capacitor bank can be kept charged as a precondition for a treatment and the stored energy can be used to excite a fast kicker magnet which deflects the beam within the specified time.

Independent operation of several treatment rooms requires mechanical beam plugs or beam stops which must completely stop the beam and render the treatment rooms safe for access. They should move into place in less than 5 seconds, or preferably between pulses for a synchrotron-based facility.

3.5.3. Monitoring of Beam in Transport System: Monitors for a fast ($t < 10 \mu\text{sec}$) detection of beam misalignment due to failures in the accelerator or beam transport system must be provided.

Monitors for a fast (response time $t < 10 \mu\text{sec}$) detection of beam misalignment due to failures in the accelerator or beam transport system (for example, beam energy or magnet power supply error) are required. Active collimators made of scintillator material at proper locations may be considered.

All beam monitoring devices which are inserted in the beam transport system during treatments must be designed so that they do not increase the beam emittance beyond the maximum compatible with the specifications in [Sec. 3.2]. This will limit the number of monitors in the beam line during treatment.

In the treatment room, *i.e.*, in the nozzle, the proton intensity is monitored in three locations independently, the centroid position of the beam is monitored in two locations, and the beam profile is monitored at the exit of the gantry and close to isocenter. See nozzle specifications [Sec. 4] for details.

3.5.4 Monitoring of Beam Transport System Components: The beam transport system must be monitored at all times while a treatment or a calibration procedure is in progress.

The beam transport system components must be monitored both by software-based systems and by hardware. See [Sec. 5].

The position of beam plugs, beam monitors and all other devices which can be inserted into the beam must be monitored in hardware and software.

3.5.5. Beam Energy Verification: An independent method of beam energy [2.1] verification must be provided. The most direct and primary method for measuring the beam energy is preferred.

One way is by providing a small momentum aperture in the transport system and monitoring the magnetic fields in the transport magnets by the treatment control subsystem independently of the accelerator control subsystem. This is to guard against malfunction in the accelerator which might produce a wrong extraction energy.

3.5.6. Gantry Safety: Safety features which prevent a collision between the patient couch and the nozzle must be provided.

The collision protection devices must be matched to the stopping time of the rotating gantry to ensure a complete stop before damage can occur.

The rotation speed of the gantry must also be matched to the braking performance. It may be necessary to limit the rotation speed when a patient is in place. The control system for gantry is specified in [5.2.6].

4. Performance Specifications for Treatment Beam Line (Nozzle)

Introduction

The nozzle comprises the devices which laterally spread the beam and modulate the range of the particles and the measuring instruments which serve as beam monitors, dosimeters and safety devices. The spreading of the particles, in depth and laterally, can be done in a variety of ways ranging from (A) purely passive methods using scattering foils and range shifting devices to (B) actively steering a narrow pencil beam by magnetically deflecting (scanning) it and changing the range of the particles many times during a treatment by changing the accelerated beam energy. If the treatment volume is scanned horizontally, vertically and in depth with the Bragg peak of a very narrow pencil beam and the scan is performed with a high enough precision, the target volume can be filled and the desired dose distribution delivered without using collimators or compensating boluses.

The scattering and scanning methods are fundamentally different. They require different beam monitoring, dosimetry and safety systems. Specifications for both methods are given in this document. Specifications are for a treatment room with a gantry unless otherwise specified. Specifications for a fixed beam different from those for the gantry beam are given.

For designing the treatment beam line and its instrumentation, see Report LBL-33403.⁸

4.1. Specifications for a nozzle using scattering

4.1.1. Scattering system: The scattering systems must be designed to modify the beam and deliver the treatment fields specified in the clinical specifications for penetration depth, field size, SAD, dose compliance, and penumbra.

The specifications for the scattering system itself follow directly from the clinical specifications for treatment depth and width [C-1, C-2, C-3], field size [C-6], SAD [C-8], dose compliance [C-7], and penumbra [C-9, C-10]. The basic system consists

⁸ W. T. Chu, B. A. Ludewigt, and T. R. Renner, "Instrumentation for Treatment of Cancer Using Proton and Light-Ion Beams," February 1993, LBL-33403; submitted to the Reviews of Scientific Instrument for publication.

of sets of two scattering foils. The first one is a "regular" high-Z material scattering foil whereas the second one is a combination of a low and a high Z material shaped in such a way that the average scattering angle is largest at the center but the energy loss is independent of the distance to the center.⁹ Each set generates a uniform field of a given diameter for a specific beam energy. The number of needed sets of scattering foils as well as the detailed design parameters depend not only on the clinical specifications but also on the number of operational beam energies, available beam currents, and the number of desired field sizes with less than the maximum diameter. For conforming the Bragg-peak dose in 3-D to the target volume and performing *variable-modulation* treatments a multileaf collimator has to be added to the scattering system. The conformation is achieved by irradiating the target volume in layers which are shaped by the multileaf collimator [6.5.4] and stacked in depth. The range shifting should be achieved preferably by varying the accelerator energy, however, in the initial phase of operation of the facility it may be accomplished using a mechanical device.

4.1.2. Beam Monitoring: Beam positions, profiles, and other attributes must be measured and monitored at specified position on the beam line during the beam tuning, calibration processes and actual treatments as specified below.

Description	During tuning	During calibration and treatments
Beam position (centroid) at first scatterer	± 0.5 mm	± 0.5 mm
Beam profile at first scatterer (resolution)	1 mm	1 mm
Beam position (centroid) at second scatterer	± 0.5 mm	± 0.5 mm
Beam position (centroid of unspread beam) at a distance of less than 1 m from isocenter	± 0.5 mm	—
Compliance of the radiation field with the expected distribution measured at a distance of less than 1 m from isocenter. ¹⁰	—	± 2 %

⁹ B. Gottschalk and M. S. Wagner, "Contoured scatterer for proton dose flattening," Harvard Cyclotron Laboratory, a preliminary report 3/29/89 (1989).

¹⁰ While a two-dimensional measurement of the beam distribution is not mandatory, it is necessary to measure the field profile at or near isocenter in two orthogonal directions with at least a 10 mm resolution.

4.1.3. Dosimetry: Three independent dosimeters that will provide continuous monitoring of the dose delivered to the patient are required.

- One dosimeter has to be located at a distance of less than 1 m from isocenter.
- One dosimeter will not saturate at the highest possible beam current focused into a 3 mm × 3 mm area.
- At least two dosimeters must measure the total beam current, whereas the third one may measure a well-defined fraction of the total field. It should be the center portion and not be smaller than 5 cm in diameter.

All dosimeters must be calibrated with a NIST-traceable standard. A secondary electron emission monitor (SEM) fulfills the non-saturating dosimeter requirement. For the calibration of the treatment dose a thimble or another standard dosimeter is placed in a suitable phantom at isocenter. Accuracy and stability of dosimeters and dosimetry system are specified in the clinical specifications [C-11].

4.1.4. Beam modifying devices: The range of the protons must be changed during the treatment covering from 1 g/cm² to 16 g/cm² in 0.5 g/cm² steps.

For variable modulation treatments the range of the protons must be changed during the treatment. The step-down in energy from layer to layer is preferably done by changing the accelerator energy, but if that is not feasible in the first phase of operation, a range shifter is to be employed. The range shifter must cover 16 g/cm² in 0.5 g/cm² steps, and must be designed to satisfy the distal dose falloff requirement [C-9]. (Note: This relaxes the clinical specifications [C-2] which call for the modulation of the Bragg-peak over the full range. It is sufficient to treat targets up to 16 cm thick. If the thickness of the treated target is limited to 16 g/cm², there is no difference.)

In order to achieve a good penumbra [C-10] it is important that the nozzle design will allow for the closest possible positioning of the beam modifying devices like patient collimator, compensating bolus, and multileaf collimator to the patient. The range shifter must either be located upstream where the beam diameter is small in order to achieve a small apparent source size or it must be located immediately upstream of the patient collimator.

For fixed Bragg-peak modulation treatments mechanical devices such as a propeller (modulator wheel) have to be provided. Depending on accelerator and beam properties it may be possible to integrate the modulating devices with the first scatterer. Otherwise, the effect of the position of the modulator wheel on the penumbra must be carefully evaluated.

The manufacture of propellers, in particular their design, size, modulation resolution and construction are strongly influenced by the design of the nozzle. Typically the construction material is water-like, such as Lexan. The size is larger than the beam size at the location of the device and may be as large as the entire radiation field. Example designs of filters for proton facilities are propeller-like with widths which cover from 1 cm to 16 cm usually in 0.5 cm steps.

4.1.5. Safety: Whenever a beam monitor or dosimeter reading is "out of tolerance" (see [4.12]) action must be taken; in most cases the beam must be shut off immediately (see [5.12]). The signal generation and therefore the readout of the beam monitoring devices and dosimeters must be fast enough to ensure that, under all circumstances, the beam can be cut off before more than 0.5% of the total treatment dose has been delivered anywhere in the treatment volume after the error condition has been identified.

4.1.6. Monitoring of positions of beam-modifying devices: All devices which can be physically moved, like scattering foils, beam monitors, etc., and can possibly interfere with the beam and alter the delivered dose distributions must be interlocked or monitored for correct positioning in software and hardware.

4.2. Specifications for nozzle using scanning

The scanning system must be designed to modify the beam and deliver the treatment fields specified in the clinical specifications for penetration depth, field size, SAD, dose uniformity, and penumbra.

By employing a three-dimensional scanning pattern the scanning system must be able to deliver a dose distribution which comply with the prescribed (in general non-uniform in a given depth of treatment) dose distribution as closely as possible.

4.2.1. Dose compliance: The dose compliance must be such that for each point inside and outside the target volume, the dose is within $\pm 2.5\%$ (2 s.d.) of the intended value [C-7].

Dose compliance is a measure of the difference between the prescribed dose distribution and that which would be delivered in the absence of imperfections in the scanning system, the beam-current control, and patient motion. Dose compliance evaluation must take into account patient immobilization, the time needed for each scan, the number of redundant scans, the control of the beam position and of the beam intensity at the target, etc.

4.2.2. Permissible beam spot size: The maximum permissible beam diameters at isocenter are: $\sigma_b^{\max} = 6$ mm at a beam energy of 250 MeV, and $\sigma_b^{\max} = 10$ mm at 120 MeV, where σ_b is the width (80%-20%) of the beam in air at isocenter. A linear interpolation is to be applied at intermediate beam energies.

It is desirable to have the steepest possible dose gradient at the lateral edges of the field. The lateral dose gradient for a scanned beam depends mainly on two factors, the width of the scanned pencil beam entering the patient (σ_b) and the multiple scattering in material including the patient. Assume the beam has a Gaussian profile, and σ_b adds in quadrature to the σ_{scatt} due to multiple scattering:

$$\text{Lateral penumbra (80\%-20\%)} \sim [\sigma_b^2 + \sigma_{\text{scatt}}^2]^{1/2}$$

The broadening of the beam due to multiple scattering is sensitive to the amount of material in the beam: the beam monitors, vacuum windows, and air, and also depends on the beam energy.

4.2.3. Length of scanning magnets: The total length of a scanning magnet must be less than 0.5 m. The aperture must clear the beam.

The shorter are the scanning magnets, the easier they can fit into the gantry nozzle and the longer becomes the SAD for a given drift space in the gantry. The clinical specifications for the field size must be satisfied by designing magnets and power supplies accordingly.

4.2.4. Scanning methods: The scanning of the treatment volume with a narrow pencil beam can be done in various ways, *e.g.*, the continuous raster scanning or the discrete voxel scanning. In the raster scanning method,¹¹ the treatment volume is continuously scanned layer-by-layer in depth with the Bragg peak. In the voxel scanning method,¹² the beam is shut off when a voxel (or spot) has received its desired dose. The beam is then moved to the next spot and switched on when a stable position has been achieved. As an alternative to deflecting the pencil beam magnetically in two dimensions, the patient may be moved in one direction and the beam deflected in the other (line scanning).

4.2.4.1. Voxel scanning system: It will be a challenge for any voxel scanning system to satisfy the clinical requirements of irradiating the largest treatment volumes in the specified treatment time while providing a small enough beam spot for satisfying the penumbra and dose compliance specifications. The largest treatment volumes can contain up to 80,000 5 mm × 5 mm × 5 mm voxels. This implies that the time available for moving the beam to the next location and depositing the dose is of the order of 1 msec.

4.2.4.1.1. Voxel scanning system:

- The uncertainty in the beam spot position due to the scanning system must be less than 0.5 mm.
- It must be possible to position the Bragg peak in the target volume in 5 mm or smaller steps in all directions, *i.e.*, the available voxel size must be less than 5 mm × 5 mm × 5 mm.

4.2.4.2. Design example of a raster scanning system: The scanning system consists of two dipole magnets sweeping the beam in orthogonal directions, performing a lateral 2-D scan. In one direction the beam is scanned rapidly and in the orthogonal direction slowly. The instantaneous scan speed in both directions should be variable (scan velocity modulation) in order to control the dose deposition as a

¹¹ W. T. Chu, B. A. Ludewigt, K. M. Marks, M. A. Nyman, T. R. Renner, R. P. Singh and R. Stradtner, "Three-Dimensional Conformal Therapy Using Light-Ion Beams," *Proc. of the NIRS International Workshop on Heavy Charged Particle Therapy and Related Subjects* (ed. by A. Itano and T. Kanai), July 4-5, 1991, Chiba, Japan, 110-123 (1991).

¹² E. Pedroni, H. Blattmann, T. Böhringer, A. Coray, S. Lin, S. Scheib and U. Schneider, "Voxel Scanning for Proton Therapy," *Proc. of the NIRS International Workshop on Heavy Charged Particle Therapy and Related Subjects* (ed. by A. Itano and T. Kanai), July 1991, Chiba, Japan, 94-109 (1991).

function of the position of the beam centroid. The beam line vacuum has to be extended as far towards isocenter as possible in order to minimize the multiple scattering of the proton beam in air which tends to increase the beam spot size beyond the limit specified in [4.2.2]. For the same reason, beam monitors and dosimeters must be as thin and placed as far downstream as possible. In this design example the vacuum extends beyond the scanning magnets. The vacuum pipe is followed by a helium bag and two ionization chambers. The dosimeters and other necessary devices can be telescoped back when space is needed for positioning the patient.

Fig. 4.1: Components of beam scanning system (distance to isocenter is given in parentheses): end of gantry (3.5 m), wire chamber (3.4 m), scanning magnet horizontal (center at 3.1 m, length 0.5 + 0.1 m), scanning magnet vertical (center at 2.5 m, length 0.5 + 0.1 m), SEM (total beam monitor) (2.2 m), vacuum exit window (2.0 m), helium bag, ionization chamber 1 serving as total beam monitor and used for beam centering (1.5 to 0.3 m, telescoped), high resolution ionization chamber (1.5 m to 0.3 m, telescoped).

4.2.4.2.1. Raster scanning parameters: The requirements for scanning speeds, their accuracies, modulations, and permissible errors are given below.

Scanning system parameters:

- maximum scan speed: 40 mm/msec (fast); 4.0 mm/msec (slow)
- minimum scan speed: 0.0 mm/msec (fast); 0.0 mm/msec (slow)

- The scan speed accuracy is specified as a function of the width of the time interval Δt during which the speed is determined or averaged:

$$\Delta t > 100 \mu\text{sec}: \quad \pm 2\%$$

$$100 \text{ msec} > \Delta t > 25 \mu\text{sec}: \quad \pm 20\%$$

On a shorter time scale ($<25 \mu\text{sec}$) the accuracy of the scan speed is unspecified.

- The scan speed must be controlled as a function of the beam position.
- The uncertainty in the beam spot position due to the scanning magnets must be less than 0.5 mm.

4.2.4.3. Beam Monitoring: Beam positions, profiles, and other attributes must be measured and monitored at specified position on the beam line during the beam tuning, calibration processes, and actual treatments as specified below.

Description	During tuning	During calibration and treatments
Beam position (centroid) upstream of scanning magnets	$\pm 0.5 \text{ mm}$	$\pm 0.5 \text{ mm}$
Beam profile upstream of scanning magnets (resolution)	1 mm	1 mm
Beam position at a distance of less than 1 m from isocenter	$\pm 0.5 \text{ mm}$	—
Beam profile at a distance of less than 1 m from isocenter (resolution)	1 mm	—
Beam current of scanned beam (given in required time resolution)	—	$<25 \mu\text{sec}$

4.2.4.4. Scanning Dosimetry: Three independent dosimeters that will provide continuous monitoring of the dose delivered to the patient are required.

- One dosimeter has to be located at a distance of less than 1 m from isocenter.
- At least one dosimeter must not saturate at the highest possible beam current focused into a 3 mm² area. (A secondary electron emission monitor (SEM) fulfills this requirement.)
- A dose detector with a two-dimensional position resolution of 5 mm or better must be provided. The detector must be able to generate a beam cut-off signal when any one spot has reached the specified dose limit. It can thus serve as one of the three independent dosimeters. (A possible implementation is a large-elements ionization chamber with matrix of 5 mm × 5 mm sensitive areas which are connected to preset scalers.)

All dosimeters must have NIST-traceable calibration. For the calibration of the treatment dose, a thimble or another standard dosimeter is placed at isocenter. Accuracy and stability of dosimeters and dosimetry system are specified in the clinical specifications [C-11].

All dosimeters scatter the beam and increase its lateral size. In order to satisfy the specifications for the maximum beam diameter at isocenter [4.1.2.] the detectors have to be made as thin as possible.

4.2.4.5. Beam energy modification: The range of the protons must be changed during the treatment covering 16 g/cm² in 0.5 g/cm² steps by changing the energy of the extracted beam from the accelerator. See [2.1.4].

No mechanical devices to modify the beam will be used.

4.2.4.6. Safety: Whenever an "out of tolerance" condition [4.1.2] is detected, the beam must be cut off before additional 5% of the treatment dose is delivered to any one spot in the treatment volume.

The general response to a beam monitor or dosimeter reading being "out of tolerance" is an immediate cut-off of the beam. The signal generation and the readout of the beam monitoring devices and the dosimeters must be fast enough to ensure that the beam can be cut off before more than 5% of the prescribed treatment

dose has been delivered to any one spot. Depending on spot size and scanning system design parameters, this specification requires the beam to be shut off in less than 25 μ sec.

4.2.5. Other Nozzle Hardware

4.2.5.1. Monitoring of positions of beam-modifying devices: All devices which can be physically moved, such as beam monitors, and can possibly interfere with the beam and alter the delivered dose distributions must be interlocked or monitored for correct positioning in software and hardware.

4.2.5.2. Collimation for patient safety: Collimation devices, either poured Cerrobend collimators or a multileaf collimator, are necessary in order to provide passive protection for the areas outside the target volume.

5. Performance Specifications for Integrated Treatment and Accelerator Control System (ITACS)

A. Introduction

In this chapter we provide performance specifications for an integrated control system which includes the accelerator control *and* the treatment delivery control for each treatment room. Requirements for interfacing to the treatment planning system and archiving data are also included.

Because the safety of a radiation therapy facility is primarily determined by its control system, it is important to illuminate what makes a control system safe. Some of the basic principles are as follows:

- *Fail-safe design* means that at each level of implementation, from the level of chips through software, the most probable failure(s), will render the system in a safe state.
- *Redundancy* decreases the probability of system failure as long as the failure mode of each sub-system is known.
- *Fault-tolerance* can be achieved by computing or measuring each variable in a matrix of overlapping processes rather than measuring or processing each variable redundantly. This approach can then be used for cross-checking and monitoring.

B. Description of Functions

In this section we briefly describe the *functions* required for the control system. The functions are grouped into:

- a set of support functions
- a set for beam delivery
- a set for beam production
- a set for operation of the facility

These functions are further subdivided as described below.

Support functions:

- 5.1. **Interlocks:** Interlocks are conditions which are prerequisites for an irradiation and expected to be steady state during an irradiation. They do not involve a control process. Examples are: power supply readiness, detector gas pressure.
- 5.2. **Beam Modification:** Beam modification is the process of tailoring the radiation field for a particular irradiation. This modification is performed by devices such as: range shifters, range modulators, beam spreaders, collimators.
- 5.3. **Beam Measurement:** Beam measurement determines radiation field parameters dynamically for control purposes to insure the correct patient treatment is delivered.
- 5.4. **Software Beam Delivery Control:** Software beam delivery control comprises the software control algorithms and procedures necessary for an irradiation. Each algorithm or procedure determines, sets, and controls the system parameters for a particular irradiation.
- 5.5. **Hardware Beam Delivery Control:** Hardware beam delivery control comprises the control functions necessary for the initiation, termination and control of an irradiation.
- 5.6. **Human Interface:** The human interface connects the integrated accelerator and treatment control system and the medical and operations personnel.

Functions for beam delivery:

- 5.7. **Monitoring:** Monitoring verifies critical conditions during an irradiation. It is comprised of a hardware and a software component. The monitoring system can only veto an operation and *cannot* initiate action.
- 5.8. **Simulation:** Simulation mimics measurement information and status to allow testing of the Integrated Treatment and Accelerator Control System (ITACS) operation without the use of beam. Use of such a system requires interlocking to prevent unintentional mixing of simulated and real data.
- 5.9. **Accelerator Interface:** The accelerator interface consists of: 1) a switch function for connecting the accelerator and a treatment delivery subsystem, and 2) a communication link between accelerator and treatment delivery subsystem. The accelerator interface provides the capability of independent operation of the accelerator and the treatment control subsystems.

Functions for beam production:

- 5.10. **Accelerator and Transport Control System:** The accelerator and transport control system controls the generation and direction of the beam to a treatment room.
- 5.11. **Timing:** This subsystem creates a set of time points which drive the sequence of events for both accelerator control and treatment control.
- 5.12. **Beam Abort/Halt:** The beam abort/halt stops the delivery of a beam into a treatment room.

Operations Functions:

- 5.13. **Dispatching:** Dispatching allocates the accelerator for the exclusive use of a particular treatment room.
- 5.14. **Prescription Server:** The prescription server is the transfer mechanism of a treatment plan between the patient treatment planning system and the integrated accelerator and treatment control system. Only prescriptions for treatments to be delivered are resident on the file server.
- 5.15. **Archiving:** Archiving is the nonvolatile recording of ITACS data. It includes both raw and processed data sufficient to reconstruct a patient treatment. It maintains an accumulative history of each patient's treatments and also provides a data base for accelerator and treatment delivery subsystem operation.

C. Performance Specifications for Control Systems

Following acronyms are used:

TCS: treatment control subsystem

TPS: treatment planning system

ACS: accelerator control system

We also define *dosimetry cycle* as the set of sequential operations that are triggered cyclically by the timing system and sequence the collection, display and monitoring of data.

5.1. Interlocks

5.1.1. Interlocks: All prerequisite, steady state conditions, not unique to a particular treatment, that must be met before an irradiation can begin must be interlocked. The following items must be interlocked:

- Personnel radiation safety circuits that restrict access to radiation areas.
- Dispatcher-enable signal that assigns the accelerator to the particular treatment room.
- Simulation status defining if the system is in simulation.
- Critical beam-line components as specified in [3.5.1, 4.1.3, 4.1.4, 4.2.4.4, 4.2.5].
- Critical power supplies whose malfunction can cause harm to a patient (*e.g.*, scanner or gantry power supply ready).
- X ray beam simulator power and position.
- Critical detector parameters which if incorrect can cause harm to the patient (*e.g.*, ionization chamber HV).

The interlock for a device must not be part of the control of that device. Status of the interlocks must be sent to the control system software and a visual display of the interlock status provided for medical and operations personnel.

5.2. Beam Modification

Beam modification devices must be controlled and specific parameters measured and monitored.

5.2.1. Collimation: The identities and positions of collimators must be monitored.

For fixed patient collimators:

- collimator(s) must be identified.
- location must be monitored if adjustable.

For a variable collimator:

- the port size and shape must be controlled to a resolution determined by the hardware device.
- the control resolution must be greater than the physical resolution of the device.
- the mechanical method of defining the aperture must be appropriately monitored.

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- times to create a port, including software control, must not exceed 1 second.
- the physical position (location and rotation) of the collimator must be monitored if adjustable.

For the movable radiation-shield collimator(s), the position(s) must be verified.

5.2.2 Range Shifting: For changing the proton range, by accelerator energy changes and/or by degraders, the energy range and step size must be controlled to satisfy the specifications [C-2, C-3, 2.1.3, 2.1.4]. The accuracy of the energy (beam range) due to software control must be better than 0.4 %.

5.2.3. Mechanical Range Compensation: Identification of the compensator must be verified.

5.2.4. Lateral Spreading of Radiation: The proton beam must be laterally spread out to produce the desired transverse dimensions, and appropriate parameters must be monitored.

For active devices the following must be defined and controlled:

- the target shape (e.g., a boundary/shape matrix of the port)
- a matrix for controlling beam motion and position
- a beam current modulation matrix as a function of beam position

Passive (double, single, or bi-material scatterer) systems must be verified for correctness.

5.2.5. Range Modulation: Energy modulation, whether achieved electromagnetically or mechanically, and whether discrete or continuously-variable, must be selectable by ITACS on an appropriate time scale. Monitoring must be performed of all critical parameters necessary to insure the beam energy is correct.

Accelerator energy changes require an established set of machine and beam transport parameters for each energy to be used. Monitoring must be

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performed of all critical parameters necessary to insure the beam energy and other beam properties are correct.

Ideally a mechanical device would automatically insert the correct filter, but installation by authorized personnel is also possible. In such a case, monitoring of the width of modulation must be performed.

5.2.6. Gantry/Patient Positioner: The gantry must be controlled for angular position with a resolution, range and accuracy as specified in [3.4.1]. The speed and the extent of rotation must also be controlled to prevent damage to the device or injury to the patient.

The control mechanism must be designed to insure rotation is not possible without proper authorization. Override of the computer control to allow manual control is required. Monitoring must be provided to insure the correct position is maintained at all times during an irradiation. Collision monitoring must be implemented to protect the patient and the equipment [3.5.6].

5.3. Measurements of Radiation Fields

Measurements must be performed in: 1) a *system unit of time*, 2) after a software *dosimetry cycle* and 3) after a complete treatment. A *system unit of time* is defined to be a time duration such that no more than 1% of the *total* treatment dose to any volume is delivered. This time is generally the time in which a beam spot delivers 1% of the prescribed dose.

5.3.1. Unmodified Beam Measurements: For a particular treatment, measurement of the beam before modification must be performed to insure proper beam conditions and for dose control.

The quantities that must be measured *per system unit time* are:

- the beam current (or intensity), *i.e.*, particles per unit time.
- the centroid position of the beam in two orthogonal planes at several locations along the beam axis.

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The quantities that must be measured *per dosimetry cycle* are:

- the integrated beam current (particles per unit dosimetry cycle)
- the beam position in two orthogonal planes at two locations.
- the dose profile in two orthogonal planes at two locations.
- the integrated delivered dose at isocenter.

The quantities that must be measured *per treatment* are:

- the delivered integrated dose at isocenter as measured by at least two independent, detectors.
- the beam range at the beginning of the treatment.

5.3.2. Modified Beam Measurements: Measurement of the beam after modification for a particular treatment must be performed for dose control purposes and must insure the radiation field is properly shaped.

The quantities that must be measured *per system unit time* are:

- beam position,
- dose as a function of position with a spatial resolution necessary to achieve the desired dose compliance.

The quantities that must be measured *per dosimetry cycle* are:

- the integrated, delivered dose at isocenter
- the integrated, transverse dose distribution with a spatial resolution necessary to verify the desired dose compliance.

The quantities that must be measured *per treatment* are:

- the integrated, delivered dose at isocenter and the integrated transverse dose distribution.

5.4. Software Beam Delivery Control

The software control algorithms necessary for an irradiation must determine, set, and control the system parameters for a particular type of irradiation. Irradiation procedures tailored for particular purposes must be provided.

The following treatment procedures must be provided; their specifications are provided below:

5.4.1. Low level exposure for exposure of film for patient alignment purposes.

5.4.2. Treatment procedure for performing a therapeutic irradiation.

5.4.3. Calibration procedures for determining calibration factors for irradiation procedure.

5.4.4. Physics application procedures for dosimetry measurements.

The following are requirements for all procedures:

- Each procedure must specify the subset of measurements to be used.
- Parameters of the ACS must be verified before an irradiation begins.
- The startup time for a procedure to the point an irradiation can be initiated must not exceed 10 seconds. (This time includes only software overhead and excludes time for interaction with medical personnel.)
- The time from initiating an irradiation procedure to commencement of the irradiation (beam on target) must not exceed 10 seconds
- The state of the irradiation must be presented to operations personnel every dosimetry cycle.

5.4.1. Low-Level Exposure Procedure: The Low Level Exposure procedure must provide the following dose control:

Minimum dose: 1 mGy

Maximum dose: 2 cGy (to prevent a therapeutic exposure)

Dose accuracy: $\pm 10\%$

5.4.2. Treatment Procedure: The Treatment procedure must provide the functions listed below to perform prescribed treatments.

- Dosimetry calibration information must be acquired from previously measured data or calculated from data-base information (of previous treatments).
- Patient setup parameters must be verified against the prescription. (Verification by medical personnel may be required.)
- Initial or previously used patient positioning parameters must be provided.
- Hardware parameters must be set to desired values.
- The state of the interlocks must be verified.
- Patient positioning device settings during a treatment must be verified.
- The state of the procedure must be saved on disk every dosimetry cycle to enable recovery in the event of an interruption caused by a computer failure.

- Halt and abort processes [5.12] must be provided.
- An abort of the beam must be executed upon treatment completion which occurs when all the steps of a procedure have been finished.
- An abort must occur upon the failure of acknowledgment of the watchdog [5.7.1].
- The treatment procedure must acknowledge the procedure-specific watchdog every dosimetry cycle within 100 msec.
- An interruption by personnel intervention, interlock dropout, critical hardware failure, a monitoring veto, watchdog acknowledgment failure, or a preset scaler trigger must be allowed. After such an interruption the state of the procedure necessary to resume a treatment must be preserved and the state of the treatment procedure restored for immediate resumption or saved under the identification of the patient for later resumption.
- Resumption of a treatment must be allowed, when after an interruption, the treatment procedure has not been exited.
- Resumption of a treatment must allow reentering the treatment procedure after either having previously exited it after an interruption or following a system crash.
- For an immediate resumption, the time to recover from an interruption must not exceed 10 seconds.
- The maximum dose uncertainty after recovery can not be greater than the dose delivered in a dosimetry cycle.
- Patient treatment data archiving and summary must be performed at the end of a treatment.

5.4.3. Calibration Procedure: The Calibration procedures must establish the conversion of the raw measured data to delivered dose at a specified location (*e.g.*, at isocenter of a target or at a detector). The following calibration procedures must be provided.

- A Dosimeter Calibration for calibrating an individual dosimeter against a certified dosimeter to test a dosimeter's performance.
- A Dosimetry Calibration Procedure for calibrating the dosimetry system for creating the dosimetry calibration reference with a required precision of $\pm 1\%$
- A Dosimetry System Reproducibility procedure for measuring the dosimetry system response for comparison against the previously created dosimetry calibration reference. The required precision is $\pm 1\%$.
- A Patient calibration procedure for calibrating the dosimetry system response to a particular radiation treatment setup against a certified dosimeter placed at the isocenter of the target volume with a required precision of $\pm 1\%$. A method for calculating calibrations from the accumulated data of patient treatments should be provided for future implementation.

5.4.4. Physics Applications Procedures: Applications procedures must be provided for characterizing the beam and radiation field properties.

The applications procedures must permit measurements for:

- an entire treatment irradiation,
- an unmodified beam irradiation,
- irradiations involving a subset of an entire treatment parameter set,
- a measurement sequence of specific, individual steps of an irradiation.

The applications must support measurements in three orthogonal axes and allow measurements in any combination of these axes, *e.g.*, water-phantom measurements. The limits and step size on each axis are: in x, y (lateral to the beam axis) directions: ± 25 cm, 0.1 cm step size; and in z direction (along the beam axis): 50 cm depth, in 0.1 cm step size.. The user must be provided with the option of defining the parameter and its value which will terminate the irradiation for each measurement, *e.g.*, clock, specified amount of time.

Both resident (permanently installed, *e.g.*, ionization chamber, wire chamber, beam spill monitor) and nonresident (installed for a particular experiment, *e.g.*, diode, water phantom, ionization chamber, wire chamber, scintillator) measurement devices must be supported for beam and radiation field characterizations.

5.4.4.1. Options for Physics Applications Procedures: Additional features that must be included in this application(s) are:

- the ability to enable or disable specific beam monitoring (only a subset of the monitoring may be required for a particular measurement).
- the ability to set beam modification devices (*e.g.*, range shifter, range modulators, gantry angles, detector position in a water phantom)
- the ability to interrupt a measurement and resume it without loss of data
- the ability to connect additional devices through I/O ports

5.4.5. Diagnostics and Tools: Diagnostics must be provide for verifying the proper workings of the system along with software tools for troubleshooting. These aids must be executable continuously or upon demand and must have restricted access.

5.5. Hardware Beam Delivery Control

Hardware beam delivery control of an irradiation must comprise the functions necessary for starting, stopping and controlling an irradiation.

5.5.1. Starting an Irradiation: Starting an irradiation must involve enabling and initiating actions. The conditions for enabling an irradiation must include:

- all interlocks satisfied,
- all watchdogs acknowledged,
- all monitoring vetoes absent.

Initiating an irradiation must include:

- receiving authorization from a qualified operator,
- controlling the beam abort/halt system.

5.5.2. Controlling an irradiation: For controlling an irradiation the delivered dose must be tracked and the beam modification devices properly controlled. Computer-read scalers and preset scalers must track the delivered dose for beam control. Device Controllers must provide:

- computer and manual control of the device operation,
- status on the device operation
- full closed loop control of the device whenever feasible.

5.5.3. Stopping and restarting an irradiation: Stopping an irradiation requires a halt and an abort action. See [5.12].

The conditions which can cause halting an irradiation must include:

- a personnel initiated halt of the treatment
- a software commanded interruption
- a computer-loaded, preset scaler firing
- a command from critical device controllers (*e.g.* gantry position).

Continuation of the irradiation must be synchronized with the accelerator upon release of the halt command. The contribution of a halt to the irradiation dose error must be less than: ± 0.1 % in any region. The conditions for aborting an irradiation must include:

- any interlock broken
- a failure of any watchdog acknowledgment
- any hardware or software monitoring veto
- a personnel initiated abort of the treatment
- any computer or manually-loaded preset scaler triggering.

An abort must preclude an immediate continuation of a treatment.

5.6 Human Interface

The human interface must provide the medical and operations personnel with graphics and alphanumeric displays, development/diagnostic tools, visual hardware-status displays, error notification and alarms.

5.6.1. Console Displays: Appropriate console displays must be provided to facilitate the operator interaction with the control system. The graphics and alphanumeric displays which provide visibility into specific system operations must meet the following requirements:

- the refresh rate of the display be at least once per dosimetry cycle,
- include a software acknowledgment of the display procedure watchdog.

The following displays are required at treatment control consoles, the setup rooms, the treatment rooms, and/or accelerator control room:

Displays	treatment control consoles	setup rooms	treatment rooms	accelerator control room
Pre-treatment information	√	√	√	
Irradiation information	√			√
Irradiation summary	√			
Patient treatment summary	√			
Facility status/scheduling	√	√		√
Beam delivery	√			√
Measurement data	√			
Alarms, error notifications	√			√

5.6.1.1. Pre-Treatment Information Display: The pre-treatment information display must provide prescription information for a treatment to allow setup of the patient.

5.6.1.2. Irradiation Information Display: The Irradiation information display must provide information of a treatment in progress and must be tightly coupled with the irradiation procedure to insure that the current state of the irradiation is being presented.

5.6.1.3. Irradiation Summary Display: The Irradiation summary display must provide the results and summary of a single irradiation.

5.6.1.4. Patient treatment summary display: The Patient treatment summary display must present a summary of all treatments for a specified patient/time period obtained from the archiving.

5.6.1.5. Facility status / scheduling display: The Facility status/scheduling display must provide the current status of patient treatments and accelerator operations for medical personnel at appropriate locations.

5.6.1.6. Beam delivery display: The Beam delivery display must provide information on the condition of the beam delivery system for a given treatment room for ascertaining its proper functioning by the operations and medical personnel.

5.6.1.7. Measurement data display: The Measurement data display must show a specified set of data, measured by user-specified detectors in a specified form (numerical or graphical) for a particular irradiation. Provision must be made for displaying Bragg curves and dose distributions.

5.6.1.8. Development/Diagnostic Tools: The Development/Diagnostic Tools must contain the displays specified above which must be capable of running concurrently. Spigots for analysis of critical signals must also be provided.

5.6.1.9. Visual Hardware Status: A direct visual hardware presentation must be provided to operations personnel to determine whether the system is in proper, working condition.

5.6.1.10 Error Notification: A means of notifying operations personnel of error conditions must be provided along with a system of permanently archiving them.

5.6.1.11. Alarms: Alarms (that will be defined at the time of a design) must have a visual and an auditory component.

5.7. Monitoring

An independent system for overseeing critical conditions during an irradiation must be provided. This monitoring system must only be capable of vetoing an operation and not initiating or controlling an action other than to terminate an irradiation. Monitoring must not be part of the control of a device. The monitoring system must include a watchdog function and general monitoring of beam modification devices, radiation properties, accelerator parameters, and beam transport parameters. When possible several means should be used to measure or deduce the same information.

5.7.1 Watchdogs: The watchdog function is a hardware-driven periodic monitoring of critical software operation. The hardware components of the watchdogs must arm themselves when triggered by timing signals. The software components of the watchdogs must acknowledge the hardware modules within the required time. A handshake must occur between the software and hardware components to complete the acknowledgment. Upon failure of a watchdog function an abort of the beam must be performed. A watchdog cycle must take place over one complete cycle of the process being monitored and must be acknowledged by software in a time not greater than 100 msec.

5.7.2. General monitoring: In general monitoring, limits (windows), boundaries (extrema) or values (specific quantities) defined either by software or hardware must be compared against an actual state or value and a determination made as to whether or not to assert a veto.

5.7.3. Beam Modification Devices: All critical beam modifying devices must be monitored.

5.7.4. Monitoring of Accelerator: Critical accelerator parameters must be monitored separately from any verification performed for accelerator control purposes. Monitoring must be performed at least every accelerator cycle, but preferable continuously during beam extraction.

The following accelerator parameters must be monitored:

- beam time structure (length, presence of spikes, absences of holes)
- beam energy or rigidity [2.1.3, 3.3.3]
- beam alignment at the exit of machine [2.3.2]
- beam profile in two orthogonal directions at the exit of machine
- beam current at the exit of machine
- accelerator parameters defining the desired accelerator state

5.7.5. Monitoring of Radiation Properties: Radiation properties before and after beam modifying devices must be monitored. The radiation properties before beam modifying devices that must be monitored include:

- beam range or quantity from which the range can be inferred.
- beam current at least every dosimetry cycle
- beam position and alignment at least every dosimetry cycle
- beam profile in two orthogonal directions

The radiation properties after beam modification occurs that must be monitored include:

- beam range
- field alignment at least every dosimetry cycle
- delivered dose at specified locations at least every dosimetry cycle
- field compliance at least every dosimetry cycle

5.7.6. Monitoring of Beam Transport System: The beam transport system must be monitored at the beam switchyard and before the first beam modification device [3.2.2]. In addition the beam abort/halt system must be monitored. The following parameters should be monitored:

- beam alignment
- beam shape
- beam current
- beam-line choice (*i.e.*, which treatment room)
- beam-line magnetic fields
- beam-line magnet currents

5.8. Simulation

A method must be provided for testing the integrated accelerator and treatment control system without the use of beam, that is capable of generating measurement information and subsystem status. Individual treatment control system and accelerator control system simulation must be provided.

5.8.1. Simulation Interlocking: This capability must be interlocked to prevent erroneous use and must be carried out to the lowest level possible.

Prerequisites that must be satisfied before simulation of a treatment room can occur include:

- a handshake must be performed with the dispatcher that the treatment room is off-line
- the proper state of the beam transport system to that treatment room must be interlocked,
- the proper state of the treatment room control system must be verified,
- the proper state of the abort/halt system for that treatment room must be interlocked.

5.8.2. Simulation Control: Independent simulation of selected accelerator and treatment control systems must be provided.

5.8.3. Simulation Information: The simulation procedures must provide:

- measurement data,
- beam-modification device control and status information,
- accelerator parameter values and responses,
- accelerator/treatment control subsystem link information (of each for the other when de-coupled from accelerator).
- beam abort/halt control and status information,
- beam-stop and beam transport status,
- timing signals which will mimic real accelerator timing, permit dosimetry cycles twice that of the accelerator cycle and allow software-programmable timing signals.
- monitoring status of the accelerator subsystems and treatment control subsystems.

Simulation of monitoring must include the capability of suppressing monitor vetoes. Such suppression must be interlocked and disabled when leaving the simulation mode.

5.9. Accelerator Interface

The accelerator interface must connect the accelerator control subsystem and a treatment control subsystem, and provide a communication link between the two. The accelerator interface must also provide simulation capability to permit independent operation of the two subsystems.

5.9.1. Software Communication Switch: The accelerator interface of a particular treatment control subsystem must provide a software switch for granting exclusive use of the accelerator to that particular treatment control subsystem. At the same time the dispatching function must set a software switch in the accelerator control subsystem allocating the accelerator to that treatment room only.

The following information must be provided by the accelerator control subsystem to the treatment control subsystem software via the accelerator interface every accelerator cycle:

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➤ continued from the previous page

- the beam energy, rigidity, current (intensity), position, shape
- the accelerator magnetic field and RF
- the necessary beam transport data (e.g., beam transmission, position, shape)

The desired energy and intensity must be provided by the treatment control subsystem to the accelerator control subsystem via the accelerator interface *every accelerator cycle*:

5.9.2. Hardware Communication: The treatment room selection made by the dispatching function must result in setting a hardware switch in the accelerator interface and a hardware switch in the accelerator control subsystem allowing only hardware signals from the chosen treatment room to go between that treatment room and the accelerator.

The hardware signals that must be sent to the treatment control subsystem via the accelerator interface are: the beam extraction status, the beam abort/halt status, and the beam-stop status.

5.9.3. Simulation: The accelerator interface must be capable of simulating all necessary data and status information for the accelerator and the treatment control system to allow independent operation of one from the other. See [Sec. 5.8].

5.10. Accelerator Control

The accelerator control subsystem must control the accelerator hardware and safely provide the desired beam characteristics for an irradiation. The accelerator control subsystem must operate the following components:

- an ion generator,
- the injection system for initial acceleration and transport of ions into the synchrotron,
- a synchrotron for accelerating the ions to the desired energy,
- an extraction system for removing the beam from the synchrotron,
- a beam transport system for channeling the ions to the desired treatment room,
- a sequencing and timing system for control of the beam,

- a monitoring system for insuring correct and safe operation,
- a system for saving and restoring the parameters of the accelerator control subsystem.

The performance of each of these subsystems must be monitored and a software check performed to insure the subsystem is functioning (alive-and-well check). The subsystem parameters that are set (set-points) must be verified.

5.10.1. Measurements of Beam and Device Parameters: Measurements of beam properties and device parameters must be provided for control, status, and monitoring. Monitoring must be performed independently from control and status measurements. Critical measurements must be traceable to fundamental standards with well-specified calibration procedures and frequency of calibration.

5.10.2. Communication Links: Several types of links must exist between the accelerator and beam delivery subsystems and their components. (The communication link between the ACS and TCS are described in the [5.9] Accelerator Interface, [5.12] Abort/Halt, and [5.13] Dispatcher sections.) Communication links between the various accelerator control functions and their corresponding components must be performed using active messaging and not common memory.

The following communication links are required:

- a Data Line for the exchange of information between subsystems and for stamping data as a certain type (*e.g.*, real beam data, simulated data, data at time of abort/halt).
- a Timing Line (see [5.11]) for synchronizing particular operations and procedures and time stamping data for control and archiving purposes.
- a Fast Protect Line that synchronizes several actions to halt/abort the beam.

5.10.3. Control Structures: The accelerator control function components must be clearly defined (*e.g.*, actuators, sensors, control parameters), along with their relationships. The set-points (values), set-point tolerances (windows) and achievable boundaries (extrema) must be incorporated into the control system.

5.10.4. Simulation: Simulation must be provided to mimic measurement information and status to allow testing of the TCS and ACS without actual beam acceleration or magnets operation.

Such a system must be interlocked to prevent unintentional mixture of simulated and real data. Simulation status must be provided to the accelerator control software, dispatching, and the archiving. A blatant visual indication of simulation for operation personnel must also be provided.

5.10.5. Save/Restore: A system must be provided for saving and restoring the parameters of the accelerator control system (*e.g.*, machine tune) in part or *in toto*.

Parameter sets for a particular machine operation must be restorable in a time necessary to meet the energy and treatment room switching required [2.1.2, 3.3.3].

5.10.6. Archiving: Archiving must be performed to allow reconstruction of the state of the system. Archived data will be used advantageously for trouble shooting and diagnosis. See [5.15].

5.10.7. Alarms and Monitors: Critical parameters of the accelerator must be monitored. Alarms based on parameter values being outside defined limits must be provided.

5.10.8. Keep-Alive: A clear handshaking or wrap around exchange protocol must exist between coupled functions to insure they are properly functioning.

5.10.9. Critical features for accelerator operation: Design guidelines listed below must be implemented.

- measure beam rigidity and emittance near the exit of accelerator,
- guarantee the beam shape and alignment (*e.g.*, by using baffles),
- permit high level orbit corrections,
- provide energy control accuracy specified in [2.1.3].
- provide self-diagnosis algorithms

5.11. Timing

5.11.1 ACS Timing: The sequencing and timing for the various, accelerator-control functions must be provided.

This time sequence must drive the TCS via a dedicated communication line. Timing must be provided for independent operation of the TCS when the accelerator is not operating. A timing system which permits dosimetry cycles twice that of the accelerator cycle and allows software programmable timing signals is highly recommended.

5.12. Beam Abort/Halt

A means of stopping the beam upon request must be provided. Its design must be fail-safe and have a halt and an abort mode of operation. Status on its state must be provided at all times.

5.12.1. Halt: A halt must turn-off the beam. The response time of this system must be such that the dose can be controlled to an accuracy of 0.1% in any region of the tumor volume. The end of a halt must be synchronized with the accelerator and dosimetry cycle. Buttons for beam halt at the treatment control station must be provided. The following conditions must cause a halt:

- an action by a qualified person (*e.g.*, pushing a halt button),
- completion of a step in an irradiation procedure,
- the monitoring system's detection of anomalies potentially hazardous to the patient (*e.g.*, motion of patient couch)

5.12.3. Abort: The abort process must turn off the beam by halting the beam and inserting a beam-stop. This action must not allow an immediate continuation. The following must cause halts:

- an action by a qualified person (*e.g.*, pushing an abort button, opening a radiation door),
- completion of an irradiation procedure,
- loss of any interlock,
- the monitoring system's detection of anomalies potentially hazardous to the patient (*e.g.*, unwanted gantry rotation).

Special dedicated hardwired links must be used to activate this function. After an abort has occurred reset of the beam abort control circuits must be performed

independently by the ACS and TCS. Buttons for emergency beam abort at appropriate locations must be provided.

More than one method for stopping the beam from entering a treatment room must exist, (*e.g.*, the beam transport system de-energized, the beam extraction system turned off, a beam stop inserted at the accelerator and treatment room).

5.13. Dispatching

5.13.1 Dispatching: A method for connecting the accelerator to a treatment room must be provided. A method for handling requests from more than one treatment room must be included.

This dispatching function must:

- receive simulation and radiation interlock status
- assess the availability of accelerator and beam transport systems
- receive requests from all treatment rooms
- allocate the accelerator only upon a request from a treatment room
- select a treatment room to connect to the accelerator based on an algorithm (This algorithm could initially be as simple as "first come first serve.")
- set a hardware switch in the ACS for exclusive use of the accelerator by a treatment room
- set a hardware switch in the selected treatment room to allow communication with the accelerator (Hardware signals from only that treatment room may then go to the accelerator.)
- set a software switch in the ACS that allocates exclusive use of the accelerator to the selected treatment room
- set a software switch in the accelerator interface that grants exclusive use of the accelerator to the selected treatment room (Software signals from only that treatment room may then go to the accelerator.)
- provide hardware and software handshakes between the dispatcher, the treatment room and the accelerator. In simulation mode handshakes must be mimicked

5.14. Prescription Server

5.14.1. Prescription Server: A function must be provided for connecting the treatment planning system with the treatment control system for the exchange of all necessary information.

This prescription server must be provided for transferring and storing the parameter sets determined from the TPS to the TCS for each patient treatment. The information exchanged between the TPS and TCS must be properly presented (in the right format) for use by the other. Results of each treatment delivered by the TCS must be available for feedback into the TPS for refinement of the treatment plan.

5.14.2. Security: Protection from unauthorized/inadvertent modification of treatment parameters must be guaranteed. A means of independent verification of patient-specific, treatment parameters before a treatment must also be provided.

5.15. Archiving:

An archive of the history of beam delivery for the entire facility must be provided. Archiving must include both raw and processed data records of the ACS and TCS for the following functions:

- Treatment Summary
- Treatment Reconstruction
- System Recovery
- Data Base Functions

All legal, privacy and security requirements on record keeping of the State of California, the Federal Drug Administration, etc. must be satisfied.

5.15.1. Treatment Summary: Treatment summaries must be provided at the end of a treatment and at the end of each treatment period.

Data records of the following must be kept:

- each treatment summary for a patient
- the summary of all treatments for a patient
- the delivered dose matrix for each treatment

5.15.2. Event Reconstruction: Critical raw and processed data records must be kept permanently for each dosimetry and accelerator cycle.

5.15.3. System Recovery: Sufficient data must be archived to allow treatment control subsystem recovery and treatment resumption at any later time. (Recovery time is specified in the treatment procedure specifications.) Data sufficient to resume irradiation operation at any later time must be saved.

5.15.4. Legal Requirements: All clinical information necessary to satisfy medical and legal requirements must be archived. This must include:

- patient identification
- tumor dose for both an individual treatment and accumulative treatments,
- dose to critical organs for both individual treatment and accumulative treatments,
- personnel involved in treatment.

5.15.5. Security: Protection from unauthorized/inadvertent modification of treatment parameters is required.

5.15.6. Data Base Functions: Archived data must be available for creation and refinement of parameter look-up tables for the ACS and TCS. Provisions must be provided for recovering data from specification of a single parameter or combination of parameters from a pre-defined list or on any pre-defined labeling of the system parameters.

6. Performance Specification for Treatment Ancillary Facilities

This Section is divided in the following categories:

- 6.1. Pre-Treatment Equipment such as Diagnostic Tools
- 6.2. Treatment Planning Software and Hardware
- 6.3. Patient Positioning and Alignment Devices
- 6.4. Beam Modifiers
- 6.5. Treatment Console
- 6.6. Machine Operation Modes
- 6.7. Safety requirements

6.1. Pre-Treatment Equipment such as Diagnostic Tools

6.1.1. Patient accrual: A computer facility must be provided which is networked to nationwide protocol control, picture archiving and computer systems, therapy planning computers, and treatment control computers.

A typical patient flow in the Department of Radiation Oncology would be that a patient will be referred to the Department for consultation by a radiation oncologist. When the patient is determined to be a proton beam therapy candidate, the patient information will be entered into database. A protocol coordinator will be notified to determine whether or not the patient can be entered into the existing or the immediate future protocols. The patient protocols as well as protocol accrual must be connected by PACS (Picture archiving and computer systems) network for nationwide information transmittal. The computer which will be used for these purposes must be able to communicate with any computers within the proton medical facility. When all these data collection are done or in place, the patient will go to diagnostic work-up.

6.1.2. Diagnostic Equipment: The diagnostic imaging equipment must be provided to furnish following capabilities:

- ability to obtain image data from CT, MRI, SPECT (single-photon emission computed tomography), Angiogram, and Gamma camera through PACS network systems for acquisition by the treatment planning computer
- the use of a flat table top insert for CT and MRI
- the ability to incorporate all the immobilization devices which will be used for treatment.
- long-term storage capability of image data from all imaging devices, such as CT or MRI, must be provided by optical disks in the Radiology Department, otherwise an optical drive must be provided in the treatment planning area.

6.2. Treatment Planning Software and Hardware

6.2.1. Treatment Planning: The therapy planning system must provide following capabilities:

- 1) dose calculation for non-coplanar beams
- 2) 3-dimensional dose calculations incorporating multiple scattering
- 3) modeling the beam delivery system
- 4) designing 3-dimensional "smeared" compensators
- 5) computing "worst-case" dose distributions
- 6) specifying the resolution of the calculation
- 7) fast dose calculations
- 8) dose-volume histogram calculations
- 9) user friendly quality of the system
- 10) various dose display options

These requirements are explained below.

- 1) Non-coplanar beams: The capability for planning non-coplanar beams must exist.
- 2) Three-dimensional dose calculations incorporating multiple scattering: True 3-D dose calculations incorporating multiple scattering effects using, for example, the differential pencil beam (DPB) algorithm must be available. The dose calculation algorithm must be tested against,

and the results must be comparable to, Monte Carlo calculations in realistic patient geometries.

- 3) Modeling the beam delivery system: The therapy planning software must be able to model realistically the beam delivery system, be it a scattered or scanned beam. This includes geometrical considerations such as non-zero source diameter and beam divergence. In addition, if a scanning beam-delivery system is chosen, an interface must exist between the Treatment Planning System and the Integrated Treatment and Accelerator Control System (ITACS, see Sect. 5) to execute the therapy plan accurately by the treatment delivery system.
- 4) Three-dimensional "smeared" compensators: The capability to design 3-dimensional "smeared" compensators must exist. A "smeared" compensator is a compensator designed to minimize the possibility of underdosing the target volume. This is generally done by replacing the nominal compensator thickness (calculated based on patient CT data) at each point with the minimum compensator thickness within some specified radius of the calculation point. This radius is selected by the treatment planner and represents the maximum distance a patient is expected to move during his/her treatment. (For skull-base tumors, this distance is generally between 0.2 cm and 0.3 cm.) The "smeared" compensator design must be included in the dose calculation (as opposed to using a "perfect" compensator).
- 5) "Worst-case" dose distributions: The therapy planning software must be able to produce "worst-case" dose distributions which illustrate the effects of patient motion during treatment as well as the effects of compensator misalignment. The program must also be capable of producing dose distributions reflecting the uncertainties in the input quantities for the dose calculation, namely the CT numbers, beam range data and beam fluence.
- 6) The resolution of the calculation: The user must be able to specify both the resolution of the calculation (*i.e.*, the points in the CT matrix at which a calculation is desired), and the CT planes on which the calculation is to be performed.
- 7) The speed of the dose calculations: The speed of the dose calculations must be such that the time required to calculate a three-dimensional dose distribution is not the time-limiting factor in the treatment

planning process. With existing technology, this is not possible if requirements 1) and 2) listed above are to be satisfied. However, it is anticipated that with the introduction of new multiple-MIP hardware in the not-too-distant future (for example, DEC Alpha VAX) such calculation speeds will be feasible.

- 8) Dose-volume histogram calculations: The software must be provided to compute and display the dose-volume histograms of selected targets and critical tissues.
- 9) User friendly: The user interface must be "friendly" in that a person with greater than one year of treatment planning experience must not have difficulties learning and using the program. A manual must be provided.
- 10) Dose display options: Isodose lines and colorwash display options must be available. On-line annotation of an isodose distribution displayed on a graphics terminal must be allowed so that the user may enter descriptive comments or notes. A hardcopy device must be available so that these annotated isodose or colorwash displays may be included as documentation in the patient's chart.

6.2.2. Requirements for image-manipulation for the therapy planning code:

Following image manipulation capabilities are required for the therapy planning system:

- 1) editing CT numbers
- 2) Window and Leveling capabilities
- 3) image magnification options
- 4) contouring modes
- 5) digitally-reconstructed radiographs (DRRs)
- 6) projecting contoured structures on DRRs
- 7) the collimator design options
- 8) image correlation of CT images with other images
- 9) beam's-eye-view alignment aids

These requirements are explained below.

- 1) Editing CT numbers: The capability to edit CT numbers must exist. This includes the option to set CT densities outside of the patient equal to zero, as well as to alter CT numbers within a specified region.

- 2) Window and Leveling capabilities: Window and Leveling capabilities must exist. The number of gray levels available must be such that none of the resolution inherent in the CT scan is lost.
- 3) Image magnification options: A capability of magnifying selected parts of images must be provided. This is especially important in contouring mode.
- 4) Contouring modes: The following contouring modes must be available: An option which draws a curved line between points entered with a mouse or track ball; a "rubber-band" option which connects points with a straight line, or smoothly interpolate between the points with splines; and an automatic thresholding mode. In addition, must a reliable automatic contouring method become available, this method must be incorporated in the treatment-planning system. A contour modification option must exist, especially for physicians reviewing contours). It must be possible to interpolate a contour on a given CT slice from other contours in the same structure on adjacent slices
- 5) Digitally-reconstructed radiographs (DRRs): The program must be able to produce DRRs. It must be possible to use any specified part of the patient's CT scans to make the DRRs.
- 6) Projecting contoured structures on DRRs: It must be possible to project contoured structures on DRRs.
- 7) The collimator design options: Options must be provided to add automatically a specified fixed margin to a collimator and to add manually or modify a variable collimator margin.
- 8) Image correlation of CT images with other images: The code must be able to display and manipulate other image data sets besides CT and MRI, *i.e.*, SPECT, Angiogram, and Gamma camera. Image correlation capabilities must exist whereby volumes-of-interest defined on one imaging modality can be transferred to another imaging modality. This must include both the correlation of two three-dimensional data sets (*e.g.*, CT and MRI scans), as well as the correlation of two-dimensional projection information with three-dimensional data sets. The transfer of dose distributions calculated on CT to other imaging modalities must be possible.
- 9) Beam's-eye-view alignment aids: The treatment planning system must be capable of producing beam's-eye-view alignment aids. These must include both DRRs, which have been discussed above, as well as "portal overlays." To produce a portal overlay, it is necessary to project the patient's bony anatomy (which has been contoured by a dosimetrist) in the beam's-eye-view and

magnify it to the same magnification as the portal image used for patient setup and alignment. The overlay is then superimposed on the portal image to evaluate how well the patient is aligned. This may be done manually, with a portal film and a transparent portal overlay, with the advent of new technology, this process could be done electronically.

6.3. Patient Positioning and Alignment Devices

Patients treated with proton beam must be well immobilized and precisely aligned with the treatment beam to take full advantage of the dose localization potential of this treatment modality. A patient support system for the gantry beam must hold the patient securely in the supine (or prone) position, and permit proton beam entry from any oblique direction, without danger of collision with the gantry or beam shaping hardware. Although the immobilization of the patient relative to the couch is the responsibility of the user, the patient support system must be able to support at least 98% of all potential patients in such a way that all points in any conceivable target can be accurately and reproducibly aligned to the beam to within ± 0.5 mm of their intended position. The couch and gantry together should have 6 degrees of freedom (3 translations and 3 rotations and should be compatible with remote patient positioning followed by transport to the treatment room, in order to minimize the setup time in the room.

Immobilization of the patient in radiotherapy has two functions: the first is simply to hold the patient still during the treatment; and the second is to allow the repositioning of the patient into the same position many times, for example, for the CT and MRI scans and for every fraction of the treatment.

6.3.1. Immobilization material in the beam: The immobilization material placed in the beam must be < 5 mm water-equivalent.

The immobilization must place as little material in the beam as possible. Such extraneous material, if thick, would degrade the beam penumbra unnecessarily and unacceptably. The immobilizing material, including the support structures such as chair, table, or pod, must not present to the beam any rapid variations in thickness, such as sharp edges, because adequately compensating for these would be impossible. Thus the acceptable material within a port must be uniform or smoothly varying with a thickness less than 5 mm water equivalent. This requirement applies to any possible direction of treatment.

6.3.2. The immobilization devices must not cause artifacts in the CT or distortions in the MRI: No ferromagnetic materials must be used in the immobilization for MRI imaging. No metal may be present in the immobilization for CT imaging, except for small fiducial markers, pieces 2 mm³ or less in volume. The immobilization must not attenuate the x-ray beam so much that the quality of the images obtained is compromised.

6.3.3. Ease of immobilization and releasing of the patient: The immobilization must allow the patient to be put in place and removed quickly, easily, and safely. The patient must be completely freed from immobilization within 30 seconds from the time of distress.

The quick removal is especially important in the case of any emergency, *e.g.*, in the case of fire or earthquake. Thus the immobilization device must be of the "quick disconnect" design, so that the patient can be completely freed up in short time from the time of distress, including the time required for staff to travel from the control area to the patient.

6.3.4. Immobilization for non-ambulatory patients: For non-ambulatory patients in the case of a building emergency it must be possible for the technologists to remove the entire immobilization assembly with chair or couch from the patient positioner, placing it on a dolly, and roll it out of the treatment room to a safe place.

6.3.5. Immobilization and patient emergency: Immediate access (<30 seconds) must be provided for the technologists to attend the patient in case of emergencies.

For certain patient emergencies, access to the patient without removal would be even desired for some procedures such as CPR or IV injection.

6.3.6. Patient alignment accuracy: The tolerance in patient misalignment is specified in this Section.

In general the requirements for the immobilization may be stated in terms of the relation of the target to the collimator and compensator. The collimator and compensator are designed to allow some misalignment of the patient and still

adequately treat the target and at the same time spare the nearby critical organ. This means that there is a margin of error all around the target as seen from the beam's eye view and the immobilization must hold the patient so the target remains inside that margin of error.

The design of the compensator allows for a margin of error in the depth of the distal surface of the target or the proximal and lateral surfaces of a critical organ, should one be just distal to the target. Change of depth (water equivalent) can occur if there is a body rotation so as to give a different entrance point of the beam or a change in the intervening tissue between the patient's surface and the distal target surface. The immobilization must control the rotation of the patient and the skin surface. (It cannot control changes in internal anatomy, such as stomach-intestinal- bowel contents, breathing, or heartbeat.) Thus the immobilization must not allow rotations or skin contour changes of a magnitude that would place the target outside its margin of error in depth.

The margins of error are specific to the different regions of the body. The basic quantities which will be specified are the translation as a rigid body, rotation as a rigid body, and the flexure of the body. The first two are straightforward but the last, which refers to any twisting, bending, or stretching of the body must be broken down into specific quantities applicable to each part of the body.

6.3.6.1. Margins of error: The allowed margins of error for the different regions of the body are specified in the list below.

The translation and rotation requirements are summarized in the table below:

Region of Body	Stability ¹³		Reproducibility ¹⁴	
	Translation	Rotation	Translation	Rotation
Head and Neck	< 1 mm	< 1°	< 5 mm	< 2°
Thoracic Spine	< 2 mm	< 2°	< 5 mm	< 3°
Lumbar Spine, Sacrum	< 2 mm	< 2°	< 5 mm	< 3°
Other parts of the body	to be specified			

¹³ Stability: The amount of movement during the time of one treatment procedure, which should not last longer than 45 min.

¹⁴ Reproducibility: At the start of any procedure the patient is placed in the immobilization and aligned to laser lines or previously determined couch coordinates. This initial alignment must bring the patient to the correct position within the numbers given here.

6.3.6.2. Control of body flexure: The immobilization must prevent the flexing of the body as described below.

Rotation limits of temporomandibular joints: <1 degree.

Bending of the spinal column per 10 cm of length < 1 degree

Flexure for this purpose includes all other movements of the body which can be specified and controlled to some extent with immobilization. Each part of the body can in general flex in different ways and thus will be described separately. In the head the primary moving part is the jaw. It can rotate about a lateral axis through the temporomandibular joints. Then the requirement is that rotation be limited to 1 degree. This correspond to approximately 2 mm of movement at the tip of the chin.

The spinal column from foramen magnum to coccyx is much like a rope. It can bend in two directions, differently for each adjacent pair of vertebral bodies. It can stretch or compress along its own axis, and it can twist about its own axis. These quantities must be specified locally, that is, on the scale of one vertebral body to the next. Thus the requirement for bending of the column is that it must be kept to 1 degree of change from the desired value per 10 cm of length along the cord. This angle is measured as the angle between tangent lines to the axis of the column.

6.3.7. Patient couch: Specifications for patient couch are given in this section.

6.3.7.1. Range of motion of the couch in gantry room: The couch which will hold the patient in horizontal position (e.g., supine, prone, or decubitus) for gantry treatment room must be specially designed to satisfy listed specifications.

- Couch motion ranges:
 - Lateral motion: ± 30 cm from table center
 - Along the body axis: > 120 cm
 - Vertical motion: from the beam center to 30 cm above the floor.
 - Table rotation around the vertical axis: ± 95 degrees
 - Table rotation around the horizontal axes: ± 5 degrees
 - Flexing under weight: <1 mm
 - Absolute table position accuracy: ± 1 mm and ± 1 degree
 - Relative table position accuracy: ± 0.5 mm and ± 0.2 degree
- Flexing under weight: It must have sufficient stability of structure, possibly combined with a dynamic feedback system to counteract flexing, to move a

98% reference man (assumed approximately 300 pounds) without perpendicular deviation of more than 1 mm over its range of motion.

- Couch motion ranges: It must have a range large enough to place any part of the 98% person on isocenter, *i.e.*, from head to toe, from side to side, from anterior to posterior.
- Thus, laterally, it must have movement of ± 30 cm from table center.
- Along the body axis, it must be able to move at least 120 cm from the position in which the end of the table is on the beam axis.
- Its vertical range of motion is governed by the requirement of the easy accessibility of the patient to get on and off (even for a patient who can walk only with the use of a cane or walker). There must also be the ease of moving a non-ambulatory patient from gurney to the table. Thus the vertical range must be adequate to bring the table top surface as high as beam center and as low as 30 cm above the floor.
- The required table rotation is around the vertical axis; specifically, ± 95 degrees of rotation about the vertical axis through isocenter is required to allow all beam entry angles to be used. Pitch and roll rotation, though not completely necessary, make the setup of the patient much simpler than trying to adjust the beam entry angle with only table and gantry rotations. A range of ± 5 degrees of rotation around the horizontal axes would be sufficient.
- The absolute table position must be accurate to within ± 1 mm and ± 1 degree so that reproducibility of position can be expected to be very good. The relative table position must be accurate to within ± 0.5 mm and ± 0.2 degree to allow very precise pre-treatment motions when required.

6.3.7.2. Couch motion control: Automatic and manual control methods of the couch motion must be provided according to the specifications listed below. The paramount importance here is the patient safety.

- The control computer must monitor couch position all the time.
- The speed of the couch motion must be variable from 1 mm/sec to 10 cm/sec so that the requirements of precise, small movements and large repositioning between ports, can both be accomplished with the required accuracy and with minimum lost time.
- Collision protection: The couch must have collision detectors to protect the patient in the event of an incorrect positioning command. There must be fixed

detectors at the corners of the couch and at least two detectors on wires which can be fastened anywhere to the couch or immobilization. Tripping any detector must stop all motion in the room, including the couch, gantry, and everything on the gantry. A reset procedure must be provided to allow the correction of the unsafe situation and the continuation of operations.

- Automatic operation for patient treatment: All computer commands must receive permission from a person in the treatment room before they can be carried out (except for the case of dynamic treatment mode as explained below); this may be accomplished through a request displayed on a terminal in the treatment room and with a affirmative response or by a permit switch at the couch. In non-patient mode (*i.e.*, any irradiation in which no patient is present), this requirement is not needed.
- Manual operation: The manual controls must include a "Dead-man" switch configuration and a "Stop" button that overrides a computer command and instantly (in 0.1 second) stops all couch motion. These controls and a position readout must be operable by a person standing at the couch itself.
- Crash off: There must be sufficient "couch and gantry power crash off" buttons placed in the room so that so that a button can be reached in 5 seconds from anywhere in the treatment room.

6.3.7.3. Couch movement for dynamic treatment: The two horizontal translations must be available for use during treatment in the event that very large field sizes are needed. Couch speed would be 2 cm/sec or less in this mode.

This use is called dynamic treatment mode. In this case, the patient would be moved in one direction dynamically under computer control during treatment. Thus lateral beam spreading would be needed in only one dimension; the effect of spreading in the other dimension would be created by the couch motion.

6.3.7.4. Patient couch/chair for fixed-beam room: For treatment in the horizontal fixed-beam room, it is expected that patients will need to be positioned in a chair in addition to a couch. For this purpose, there must be either a chair attachment to a couch, or a stand-alone chair. Either way, the chair must have all the motions required for the couch above, namely, 3 translations and 3 rotations.

- The horizontal translations must allow excursions of ± 30 cm about the body center and motion along the patient axis (height change above floor) must be adequate to allow treatment from near the top of the head to the top of the pelvis. This requires 120 cm of vertical motion. To accomplish treatment to the head requires a beam height above the floor of at least 150 cm (or a pit for the patient's feet with a floor level at 150 cm below the beam line).
- Provision of at least ± 10 degree pitch and roll is required since the beam is fixed and larger variations of ± 20 degrees would be even better to accommodate the desire to bring the beam in to the patient at a slight oblique angle. Full rotation of ± 185 degrees about the vertical axis is required in order to use any beam angle in the axial plane.
- All controls of the motion of the chair must be the same as for the couch, except that for dynamic mode it is the vertical and the horizontal motion perpendicular to the beam direction which must be available for movement during treatment.
- The speeds of the chair motions must be the same as the couch speed described above.
- The accuracy and precision required is the same for the chair and the couch.
- Collision detectors will also be needed as described above.

6.3.8. Patient Alignment: The process and requirements for the precision alignment of the patient to the collimator, compensator, and proton beam line are described in this section.

6.3.8.1 Coordinate System: All positions and movements must ultimately be stated in terms of the room coordinate system described below.

In each treatment room there will be a coordinate system with its origin at a point along the beam axis, at the center of a gantry's circle of rotation or of a couch rotation for a horizontal beam line. This point is called isocenter. For both rooms the first axis is vertical. The second is horizontal in the plane of gantry rotation (or perpendicular to the beam line in the horizontal beam line room). The third is perpendicular to the plane of gantry rotation (or along the beam line in the horizontal room). The directions of the axes must be so as to form a right handed coordinate system.

6.3.8.2. The Alignment Process: The process of aligning the patient is described below.

The process of alignment will first make use of lasers for the rough alignment of external anatomy or marks on the immobilization to laser lines marking the three axes of the coordinate system. But final alignment is performed with x rays imaging internal anatomy. These images are compared with images from the treatment planning showing the desired relation of the collimator, compensator, and isocenter to internal anatomy. Then the positioner will move the patient to the correct position.

For many patients this must be done in the treatment room. The precision needed for many treatments requires that the time between alignment and the beginning of treatment be kept to a minimum. Initially the alignment will likely be done with film, but eventually a digital imaging system will be required so that the time between the start of the imaging to the presentation of the image to the person who must make the decision about moving be no more than 10 seconds.

Then for other patients whose precision requirements are not so great, there must be a separate area outside the treatment room itself where the alignment procedure can take place. This area must have the same lasers, x-ray tubes, film holders, and patient positioner in the same geometry as the treatment room itself. After alignment in this room the patient in the immobilization will be moved to the treatment room, positioned to the determined couch or chair coordinates, and treated.

6.3.8.3. Equipment for Alignment: The equipment needed for alignment and the manner of use are described below.

Both areas must have the following equipment:

- 1) A set of orthogonal lasers which have a reproducible accuracy of ± 0.5 mm at isocenter. They must comply with the Center for Devices and Radiological Health regulations for Class II lasers. The laser lines must be clearly visible in normal bright room light.
- 2) X-ray tubes to give standard orthogonal views of patient anatomy (*i.e.*, AP and lateral) and beam's eye view for all directions in which that's possible. If possible they must have the same SAD (source to axis distance) as the effective SAD of the proton beam. The x-ray sources must be able to be positioned on the room axes to an accuracy of .5 mm. The tube which will give the beam's eye view must be positionable to within .5 degrees of the particle beam direction.
- 3) An x-ray detection system. Although the initial detection system is likely to be film, there must be the capability for a digital imaging system. If an adequate digital system is available at the time the room is built, then that is what must be installed. The detection system must have a spatial resolution to give a pixel size of .5 mm or less for a plane through isocenter.

Furthermore, the imaging system as a whole (sources plus detectors) must be efficient enough so that all the needed images at one patient position (frequently 2 orthogonal views) may be taken within 10 seconds. This may be accomplished by using many sources and detectors or by rapid repositioning of the hardware items. The system must not interfere with treatment and must comply with all applicable safety codes. The system must display the positions of isocenter (*i.e.*, cross-hairs) in all views and the field edge (collimator shape as projected onto the plane through isocenter) in the beam's eye view on top of the patient's anatomy. All images must have the same magnification and divergence.

A digital imaging system must work in conjunction with the treatment planning system. There must be the capability of displaying the digital, possibly enhanced, images on monitors throughout the department within 10 seconds after capture. There must be the ability to display images from the treatment planning system on top of the digital setup image and for a person to manipulate one of the images in order to determine any movement needed to put the patient in the correct place. The system must then calculate the needed move and after receiving permission from the technologist in the treatment room perform the actual move.

The separate setup room must have the same imaging geometry and capabilities as the treatment room. This may be achieved by mounting x-ray units on a gantry in which they may rotate around the patient and keep the same radius as the x rays in the treatment room. If the source-to-patient distance for the gantry is more than about 2 to 2.5 m., it might be difficult to use such a distance. In this case, a different geometry would be required and divergence corrections would be required in the treatment planning program to provide a prediction for the appearance of the setup x ray. There must be a positioner in this room which has the same position readout coordinates as the one in the treatment room. After the correct position is achieved, it must be possible to transport the patient between the external setup area into the treatment room without significantly altering the patient position. This means that it must be possible to dock the pod with the gantry simply and reproducibly. The docking mechanism must have reproducibility of ± 1 mm when a pod setup is transferred from a pre-treatment room to a treatment room.

6.2.3.8. Patient position verification: Verification of the patient target relative to the beam requires the use of isocentric lasers, isocentric diagnostic x-ray tubes and radiographic detectors. These detectors could be x-ray film cassettes or digital portal imaging devices. Manufacturers must, as a minimum, show compatibility of any facility designs with these devices.

6.2.3.9. Isocenter: In each treatment room, the isocenter, and associated coordinate system, must be defined and all positioning and movement must be referred to the isocenter.

The precision aligning of the patient to the collimator, compensator, and proton beam is the final critical step before actual treatment. In each treatment room there will be a coordinate system with its origin at a point along the beam axis, at the center of a gantry's circle of rotation (see [3.4.2]) or of a couch rotation for a horizontal fixed-beam line. This point is called isocenter. All movements of the patient will be related to this coordinate system.

6.2.3.10. Laser and x-ray localizers for alignment aid: For each treatment room, four¹⁵ each orthogonal alignment lasers and x rays must be provided according to the following specifications.

- (a) Reproducible accuracy of lasers ± 0.5 mm at isocenter.
 - (b) Positioning accuracy of the x-ray sources ± 0.5 mm. The x ray on the beam axis must be positionable to $\pm 0.5^\circ$ of the beam direction.
- (a) The process of alignment will first make use of lasers for the rough alignment of external anatomy or marks on the immobilization to laser lines marking the three axes of the coordinate system. A set of four orthogonal lasers which have a reproducible accuracy of ± 0.5 mm at isocenter. They must comply with the Center for Devices and Radiological Health regulations for Class II lasers. The laser lines must be clearly visible in normal bright room light.
 - (b) But final alignment is performed with x rays imaging internal anatomy. These images are compared with images from the treatment planning showing the desired relation of the collimator, compensator, and isocenter to internal anatomy. X-ray tubes to give standard orthogonal views of patient anatomy (*i.e.*, AP and lateral) and beam's eye view for all directions in which that's possible. If possible they must have the same SAD (source to axis distance) as the effective SAD of the proton beam. The x-ray sources must be able to be positioned on the room axes to an accuracy of 0.5 mm. The tube which will give the beam's eye view must be positionable to within 0.5 degrees of the particle beam direction.
 - (c) Then the positioner will move the patient to the correct position.
 - (d) To maintain smooth patient flow in the treatment rooms, the time between alignment and the beginning of treatment be kept to a minimum. Initially the alignment will likely be done with film, but eventually a digital imaging system will be required so that the time between the start of the imaging to the presentation of the image to the person who must make the decision about moving be no more than 10 seconds. If an adequate digital system is available at the time the room is built, then that is what must be

¹⁵ Three orthogonal directions originating at the isocenter are: along the beam direction and downstream of the isocenter, vertically up direction, and orthogonal to these two directions. For convenience, two alignment aid units are needed at both side of the beam, therefore four units of lasers and x rays are needed.

installed. The detection system must have a spatial resolution to give a pixel size of 0.5 mm or less for a plane through isocenter.

- (e) Furthermore, the imaging system as a whole (sources plus detectors) must be efficient enough so that all the needed images at one patient position (frequently two orthogonal views) may be taken within 10 seconds. This may be accomplished by using many sources and detectors or by rapid repositioning of the hardware items. The system must not interfere with treatment and must comply with all applicable safety codes. The system must display the positions of isocenter (*i.e.*, cross-hairs) in all views and the field edge (collimator shape as projected onto the plane through isocenter) in the beam's eye view on top of the patient's anatomy. All images must have the same magnification and divergence.
- (f) A digital imaging system must work in conjunction with the treatment planning system. There must be the capability of displaying the digital, possibly enhanced, images on monitors throughout the department within 10 seconds after capture. There must be the ability to display images from the treatment planning system on top of the digital setup image and for a person to manipulate one of the images in order to determine any movement needed to put the patient in the correct place. The system must then calculate the needed move and after receiving permission from the technologist in the treatment room perform the actual move.

6.2.3.11. Simulation room: Simulation room must be provided to pre-set up the patient outside of the treatment room.

- For certain patients whose alignment requirement is less stringent than those requiring precision alignment in the treatment room, there must be a separate area outside the treatment room itself where the alignment procedure can take place. This area must have the same lasers, X-ray tubes, film holders, and patient positioner in the same geometry as the treatment room itself.
- The pre-setup room (simulation room) must have the same imaging geometry and capabilities as the treatment room. This may be achieved by mounting x-ray units on a gantry in which they may rotate around the patient and keep the same radius as the x rays in the treatment room. If the source-to-patient distance for the gantry is more than about 2 to 2.5 m,

it might be difficult to use such a distance. In this case, a different geometry would be required and divergence corrections would be required in the treatment planning program to provide a prediction for the appearance of the setup x ray. There must be a positioner in this room which has the same position readout coordinates as the one in the treatment room. After the correct position is achieved, it must be possible to transport the patient between the external setup area into the treatment room without significantly altering the patient position. This means that it must be possible to dock the pod with the gantry simply and reproducibly. The docking mechanism must have reproducibility of ± 1 mm when a pod setup is transferred from a pre-treatment room to a treatment room.

6.4. Beam Modifiers

It is assumed that passive scattering and fixed modulation will be initially used to create a treatment beam which is spread uniformly in 3 dimensions. In this case, it must be possible to produce compensators which are patient and portal-specific. These compensators could also include the specific energy degrader needed for that portal (assuming that the beam energy from the machine is selected to be close to that needed for the treatment). The compensator and beam-defining collimator must be mounted very close to the patient. The best way might be to mount them directly to the immobilization device, so that they are reproducibly positioned with respect to the target. Special thought must be given to mounting structures which will not impede the gantry. It might be necessary to attach the collimator and compensator to the gantry itself, but then it must be possible to move the gantry and/or couch so that these beam modifiers are as close as possible to the surface of the patient. At a latter stage, variable modulation and beam scanning techniques may be used for treatment. The treatment system must be capable of interfacing to any of the three techniques:

6.4.1. Beam modifiers for fixed modulation:

In a fixed modulation technique, the Bragg peak is modulated over a range of depth using devices such as binary ridge filters or propellers. The maximum thickness of the tumor determines the amount by which the range is modulated. The beam is modulated to cover the thickest part of the target volume and 3D

compensators are used to account for skin surface curvature and variation of the distal part of the target volume.

6.4.2. Beam Modifiers for variable modulation: See [4.1.4].

In case of variable modulation technique [D.3], the target volume is scanned in depth by stacking the mini-spread Bragg peaks, whose modulation is roughly 1 cm and varying the modulation of the beam during treatment. The most distal layer in the target volume is scanned first. The range of the mini-spread beam is then shortened and the shape of the dynamic collimator is adjusted to scan the next layer. This process continues until the entire volume has been treated.

In beam scanning technique, the beam spot is moved continuously in a raster fashion across the radiation field. By "controlling" the scan speed and the intensity of the beam, desired dose in the field can be obtained [4.2.4.2]. The requirements for beam modifiers must satisfy the purpose of fixed and variable modulation and beam scanning techniques to be able to use any of these methods.

For requirements for treatment beam, see [Sec. C] and [Sec. 4].

6.4.3. Fixed aperture collimators: Capability of making irregular shape collimators:

Material: Cerrobend, Brass up to 20 cm diameter

Max. Size: 40 cm × 40 cm

Min. size: 1 cm circle

6.4.4. Multileaf collimator: A computer controlled multileaf collimator for dynamic aperture must be provided.

Leaf height: 1.0 cm for 40 cm × 40 cm field size

0.5 cm for 15 cm × 15 cm field size

Leaf thickness: sufficient to stop 250 MeV protons

Leaf speed: > 3 cm/sec (to change the position of leaves)

6.4.5. Compensation: The compensators will be made, either by band saw cutting of Lucite or by milling wax.

Recommended material: Lucite, Wax

- For Wax compensators:

Max. Block Size: 42 cm × 42 cm × 25 cm

Max. Field Size: 40 cm × 40 cm

Drill position accuracy: ± 0.1 cm

Drill Sizes: a set of drill sizes ranging from 0.2 cm to 1 cm

- The milling machine must be computer controlled. The milling machine must have simple hand-shaking mechanism in such a way that the output of the treatment planning data must be electronically transferred to the milling machine control for automatic compensator fabrication.
- Band saw cutting of Lucite: This mode is also available in case computer control dose not function.

6.5. Facilities for Treatment Procedures

6.5.1. Treatment consoles: The treatment console area must be located as close to the patient treatment area as possible. If at all possible it must be located just outside the exit of treatment room (maze).

The treatment console area consists of a console desk large enough to put all equipment needed to carry out the treatment safely and with ease. Such equipment includes machine parameter monitor screens, patient treatment parameter monitor, minimum of two sets of continuous patient monitoring devices and communication devices.

- The control desk must have a safe storage drawer so that the treatment door lock can be stored when the treatment room is not in use.
- In addition the treatment console area must include space for the related computers, printers, book shelves, etc.

6.5.2. Intercoms in treatment console areas: There must be minimum of two communication methods

- 1) one is intercom between the console area and the patient in the treatment room, and
- 2) another between the console area and the accelerator console area and/or the entire facility.

- This communication mechanism must satisfy the requirement described in "Overall Control System"

6.5.3. Record and Verification:

Treatment parameters such as couch coordinates, gantry angle, collimator opening and orientation, the use of compensator, Cerrobend or brass beam shaping device, beam type, beam energy, or any relevant information must be stored in a centralized area for comparison with the parameters obtained from the treatment planning and/or simulations.

These stored and intended patient setup parameters must be monitored and compared continuously with parameters being setup by radiation therapist and operator for verification. If any single pair is different from each other by more than the tolerance set in this document, the computer must warn the therapist and operator, and the treatment beam shall not be delivered to the room the patient is being setup. If they agree, each item must either be highlighted or indicated by other means. If all items agree, the computer must say on the screen that patient treatment is "READY". Only then, the therapist or operator can initiate the treatment beam. During the "Dynamic Treatment", the computer must be capable of tracking the beam, patient and machine parameters continuously for proper treatment. The time course of the live parameters must be stored someplace for later reviews. If any live parameter differ from the intended parameter, beam delivery must stop immediately and the failed parameter must be indicated. It is desirable that the cause of the failure is immediately assessable.

When the beam delivery is terminated by any reason, all beam, patient setup and machine parameters must be accessible for operator and the engineer for their examination: desirable that these information must be available in hardcopy and must be stored in a computer.

6.6. Machine Operation Modes

6.6.1. Patient Monitoring: There must be at least four different operation modes available for the proton medical facility:

1. Morning check out mode
2. Treatment Mode
3. Physics Mode
4. Special Mode

These minimum five modes must be easily programmable for radiation therapists:

1. Morning check out mode -- This mode allows radiation therapists or operators to gather and check all the necessary accelerator parameters that would be required by the accelerator engineers to solve problems if the accelerator or its accessories malfunction. This mode must include the morning warm-up procedures that are deemed necessary
2. Treatment Mode — actual treatments by radiation therapists to treat the patients. This mode is operable only if all of the patient information and patient treatment setup files are complete; at the end of the procedure a patient treatment record is produced.
3. Physics Mode — same as Treatment mode except it permits irradiations without any patient.
4. Special Mode — Allow the technical staff to operate the facility bypassing certain interlocks for the purpose of debugging or measurements, for example.

6.7. Safety Requirements

The safety of the entire system is of paramount importance. While safety is difficult to specify, a safe system will include redundant guards against any conceivable failure mode. Specific attention must be given to beam delivered outside the chosen target area, incorrect dose rate, incorrect total dose, collisions of patient with nozzle components, avoidable exposure to facility workers, and accidents involving fire, electrical or vacuum systems. Control system hardware and software must pass strict safety and quality assurance tests. The entire facility will be required to meet relevant federal and state safety standards for patient treatment devices. Control systems and all patient-related hardware must be designed to be "fail-safe", that is, the consequences of a failure cannot compromise the safety of the patient or the facility.

The principle of Mechanical, Electrical, Fire, Radiation, and any other safety for the proton therapy facility shall be based on a "fail-safe" philosophy, *i.e.*, any malfunction in the chain of interlock mechanism is such that the patient safety must be considered first.

6.7.1. Patient Monitoring:

There shall be a minimum of two pairs of cctv camera and CRT screen operable for continuing viewing of the patient during treatment. This continuous patient monitoring devices must have focus, iris adjust and zoom capability. A

combination of two cctv cameras are located in such a way that the entire treatment room must be observable from the treatment console area.

There shall be a minimum of one intercom between the treatment console area and the treatment room operable for verbal communication between the patient and radiation therapists and/or radiation oncologists during treatment. The communication through Intercom must be clearly audible to every party involved in the communication.

6.7.2. Emergency Buttons:

There will be a three level of power off emergency buttons. They must be clearly marked and must be distinguishable from each other both in shapes and colors.

- 1) cut off the power to the entire facility (level one emergency
- 2) cut off the power to the room and equipment a person is working (level two emergency). The beam must not leave the accelerator or be diverted to the beam dump within 10 μ sec after this button is pushed. The room light must not go out in this mode.
- 3) divert or turn off the beam within 10 μ sec to the beam dump after the button is pushed (level three emergency).

There shall be a minimum of one level two emergency button in each of treatment console area, where radiation therapists are located during treatment.

There shall be at least one level two emergency button located on each side of a patient treatment couch and at least two more at the strategic locations in the treatment room; for example, on the wall opposite of the treatment couch. All emergency buttons shall be located at the clearly visible locations. They shall be protected from the accidental activation of the buttons.

The accelerator control console must be equipped with one Level one and one level three buttons. Any radiation hazard areas must be equipped with one level three emergency button. These area include beam switch yard and beam transport area.

6.7.3. Door Interlocks:

There shall be at least two electronics switches located on the door or door jamb. These switches shall function as the level three emergency button and thus stops the radiation exposure within 10 μ sec when the door was opened by more than 3 inches. Closing of door shall not cause the radiation to be resumed. The radiation

shall resume only when door is closed and the operator initiates the exposure, assuming that all the other interlocks are properly set.

6.7.4. Radiation Monitor:

A red and white light shall be located above the treatment room door. The white light shall be turned on whenever the accelerator power is turned on without the beam in the accelerator and beam lines. The red light at the entrance of each treatment room shall be flashing during the delivery of the beam to that treatment room.

The control console shall be equipped with an indicator indicating that the accelerator's main power is on. It shall also be equipped with an indicator indicating that the beam is being delivered to that room and that high radiation exposure exists during the beam-on mode.

There shall exist a communication mechanism between the accelerator operators and radiation therapists for delivery and instantaneous ceasing of the beam; for example, electronics communication using CRT screen and a backup mechanism (such as intercom) in case the former fails to function.

There must be an alarm system which must sound "alarm" and initiate red light flashing should any one of radiation monitors placed in strategic places read more than the limits set by the State of California, by the local authorities, by the UCD Medical Center or any other authorities who have jurisdiction over the proposed Proton Treatment Facility. The alarm system must simultaneously trigger either to divert the beam or shut off the power to an accelerator so that the radiation readings in the entire facility accessible to all personnel in the facility including patients and visitors must instantly become less than the limits set by the above mentioned authorities.

Neutron levels at 1 m from the isocenter must be less than 0.1% of the dose at the isocenter.

6.7.5. California State Regulations:

All safety features shall meet the requirement by the State of California. Even if some features are not required by the State, the selected manufacture should consider "Redundancy" on every phase of Safety Mechanism.

6.7.6. Mechanical Safety:

Patient couch, gantry and any other treatment aids in contact with or adjacent to the patient shall be locked or "frozen" as soon as the power is cut off either by activating one of the emergency buttons, power failure or intentional power shut-off.

There shall be a collision interlock mechanism whereby the power shall be cut off upon the contact of the patient couch with a gantry and any other patient treatment aid devices.

In case of power failure, there shall be emergency light turned on in the treatment room, possibly in the treatment maze, a hallway leading to the patient waiting area, and any other locations so that the patient can be easily and safely evacuated to safe locations designated by the University's fire evacuation plan.

A gantry and couch design must include the consideration such that the radiation therapists can easily mount and dismount the blocks and compensators on or from the gantry nozzle. For example, there must be a platform or equivalent from where the therapist can reach the field size defining collimators or devices, blocks and compensator without leaning over and against the couch or the gantry. In the event that the any one of these accessories exceed the weight of 35 lbs, a hoist or similar tool must be available to transport such devices from the storage cabinet to the set locations and vice versa. Such device must be located safely away from the patient and the staff so that they do not get hurt accidentally.

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D. Appendix

D.1. Spreading the Bragg peak

Dose in Gray is defined by the amount of energy deposited in a volume by particles traveling through or stopping in that volume.

$$D(\text{Gy}) = 1.6 \cdot 10^{-9} \frac{dE}{dx} \left(\frac{\text{keV}}{\mu} \right) N_p \left(\frac{\text{p}}{\text{cm}^2} \right)$$

For a given treatment, the Bragg peak is generally spread out by varying the proton energy entering the patient, thus varying the range in the patient. The highest energy protons define the distal extent of the irradiated tumor volume, but they also deposit energy, albeit at a lower rate, upstream of the end of the range. Therefore, less stopping intensity is necessary in upstream elements of the tumor volume, as some dose has already been deposited there.

Fig. D.1. Shown are the dose distributions as a function of penetrating depth of (a) a pristine beam and (b) a beam whose energy is modulated to widen the stopping region. Such a curve with a spread-out Bragg curve has several regions referred to as the plateau, the proximal peak, the distal peak, and the distal dose-falloff edge.

D.2. Transverse spreading of the heavy charged-particle beams

The *scattering method*, the first beam spreading system used clinically, spreads the pencil beam transported to a treatment area using scattering foils.^{16,17} A variation of the scattering method that uses a combination of specially shaped scatterers of two different materials has been devised and is now used for proton beams at the Harvard Cyclotron Laboratory⁹ and the Loma Linda University Medical Center Proton Therapy Facility. Even though the beam utilization efficiency approaches ~50% with the LLUMC scatterer, the main disadvantage of the scattering systems is their stringent requirement of aligning the beam axis with the scatterers.

Several schemes have been proposed to spread the beam laterally without resorting to the use of scattering material in the beam path. Multipole magnets have been considered to spread the beams^{18,19} however, this method may require unacceptably long (order of 100 m) throw arms.²⁰ At LBL, a *wobbler* beam delivery system has been developed.²¹ The wobbler system works so well that, since its inception in 1987, it has been in use for all patients treated with large fields at LBL. The wobbler system is the beam-spreading system of choice of the Heavy-Ion Medical Accelerator at Chiba (HIMAC),²² under construction at the National Institute of Radiological Sciences (NIRS) in Chiba, Japan. Recently LBL has developed a *raster scanner* beam delivery system and used in its clinical trials.

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- ¹⁶ K. Crowe, L. Kanstein, J. T. Lyman and F. Yeater, "A large field medical beam at the 184-inch synchrocyclotron," LBL-4235, Lawrence Berkeley Laboratory, (1975).
- ¹⁷ A. M. Koehler, R. J. Schneider and J. M. Sisterson, "Flattening of proton dose distributions for large-field radiotherapy," Med. Phys. 4, 297-301 (1977).
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- ¹⁹ P. F. Meads Jr., "A nonlinear lens system to smooth the intensity distribution of a Gaussian beam," IEEE Trans. Nucl. Sci. NS-30, 2838-2840 (1983).
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- ²² K. Kawachi, T. Kanai, M. Endo, Y. Hirao and H. Tsunemoto, "Radiation Oncological Facilities of the HIMAC," J. Jpn. Soc. Ther. Radiol. Oncol. 1, 19-29 (1989).

Fig. D.3. Schematic illustration of the variable-modulation beam delivery methods and the 3d Dynamic Conformal Therapy Delivery

D.3. Variable modulation vs. fixed modulation of the width of spread-out Bragg peak; technical implications

We ascertain the advantages of the *variable modulation* method in which the width of the spread-out Bragg peak is varied according to the local width of the target volume as depicted in Fig. D.3. The gains depend very much on the circumstances of each case, but one may expect reductions in the "integral dose" in the range of 8% to 18%, and even larger gains if the integral dose calculation is restricted to regions outside the target volume.^{23,24} Here, the integral dose means the dose integrated over a volume in question; it is a non-physical quantity used as a descriptive clinical parameter and has a dimension of dose-volume. These results are generally borne out in the analysis of actual clinical cases.²⁵ A *3d dynamic conformal therapy delivery* (3D DCTD) technique is schematically illustrated in Fig. D.3, showing the dynamic collimator and range stacking using beams of *mini-spread* peaks. The two illustrated slices (M and N in the

²³ G. T. Y. Chen, S. Pitluck and J. T. Lyman, "Heavy Charged-Particle Treatment Planning," in *Biological and Medical Research with Accelerated Heavy Ions at the Bevalac, 1977-1980* (eds. Pirruccello, M.C. & Tobias, C.A.), 325-331 (Lawrence Berkeley Laboratory, 1980).

²⁴ M. Goitein and G. T. Y. Chen, "Beam scanning for heavy charged particle radiotherapy," *Med. Phys.* **10**, 831-840 (1983).

²⁵ M. M. Urie and M. Goitein, "Variable versus fixed modulation of proton beams for treatments in the cranium," *Med. Phys.* **16**, 593-601 (1989).

diagram) demonstrate the need for intensity modulation that has to be accomplished by either modulation of the scan speed and/or the beam intensity.

In raster scanning, the beam is deposited in the treatment volume as prescribed in the treatment plan. The dose distribution is given as a function of the three-dimensional coordinates of the treatment volume. If the raster speed is kept uniform, the intensity must be modulated to satisfy the distribution of dose in the treatment slice, similar to scanning a television image.

An alternative is to vary the sweep rate and to maintain a constant beam intensity. Varying the extracted beam intensity from an accelerator using a resonant extraction system is a highly nonlinear process, especially if the extraction rate goes to zero, as the feedback loops are broken, and the next appearance of beam may cause a large transient. On the other hand, varying the raster speed at the treatment site is a linear process, more amenable to analysis, as the extraction system is now operating closed-loop and steady-state, and within the velocity limits of the scanner, a wide dynamic range of dose can be deposited within the treatment volume.

D.4. Various beam-scanning methods

For the purpose of discussion, we define two modes of beam scanning. (1) In *raster scanning*, a beam spot is moved continuously in a raster fashion across the intended radiation field. If the scan speed and the beam intensity are kept constant, a uniform dose field results. To modulate the dose within the field, the scan speed and/or the intensity are modulated. LBL has developed a raster-scanning beam delivery system to broaden ion beams into large flat radiation fields.²⁶ Recently, ACCTEK Associates has produced a raster scanner for proton therapy,²⁷ and INS, Novosibirsk, has developed a fast-cycling raster scanning system (fast-scan rate at 1 kHz).²⁸ (2) In *spot scanning*, a beam spot is positioned at a given location in the field, and a predetermined amount of radiation is deposited. The spot is then moved to the next position, and the process is repeated. In order to achieve a satisfactory dose uniformity, the beam spot is moved not more than half its width. In the spot scanning system developed at NIRS, Chiba, for

²⁶ W. T. Chu, T. R. Renner and B. A. Ludewigt, "Dynamic Beam Delivery for Three-Dimensional Conformal Therapy," *Proc. of the EULIMA Workshop on the Potential Value of Light Ion Beam Therapy*, November 3-5, 1988, Nice, France, 295-328 (1988).

²⁷ R. L. Martin, "private communication (1992).

²⁸ G. Silvestrov, "private communication (1991).

70-MeV proton beams,^{29,30,31} considerations of multiple scattering of protons in the treatment volume (patient) and the edge matching of neighboring pixels make the smallest acceptable size of the pixel bigger than 1 cm by 1 cm. In this system, the beam utilization efficiency had to be severely sacrificed (<1%) by collimating the beam to obtain a small beam spot with small divergence. A prototype scanning system for proton beams has been built at the PSI, Villigen.^{32,33}

Scanning systems can produce large uniform dose fields without the use of any scattering material in the beam. The absence of material in the beam path means that longer-range beams are available for a given energy of accelerated particles, and background radiation (neutrons and induced activation) are reduced. However, the more clinically pertinent advantages of scanning over scattering are: First, the width of the lateral dose falloff of the treatment field is made sharper by reducing the beam spot size, beam divergence, and angular confusion of the beam particles. Second, the peak-to-plateau dose ratio is increased, in some designs, by increasing the effective source-to-target distance. Third, the scanning method is inherently amenable to DCTD. And finally, when used on a rotating gantry with a limited throw distance, a scanning method can achieve generally bigger fields than what is achievable with a scattering method. For certain designs of compact gantries, the use of a scattering system for beam broadening is not suitable and the use of a scanning system is mandatory. All these reasons point to the use of scanning systems in future medical accelerator facilities.

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 - 33 R. Bacher, H. Blattmann, T. Boehringer, A. Coray, E. Egger, E. Pedroni, M. Phillips and S. Scheib, "Development and First Results of Discrete Dynamic Spot Scanning with protons," *Proc. of the International Heavy Particle Therapy Workshop (PTCOG/EORTC/ECNEU), Paul Scherrer Institut, September 1989*, Villigen, Switzerland, 9-12 (1989).

Emittance Growth From Material in the Beamline

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9 October 1992

Material present in the beamline from the accelerator to the isocenter introduces scattering in the beam, increasing its emittance and therefore the size of a focused spot.

This note illustrates the emittance increase for a typical nozzle configuration consisting of a minimal number of devices in the beam: a wire chamber, a SEM, a vacuum window, and beam transport through a helium bag to near the isocenter.

The code used calculates the rms small angle scattering and rms increase to the energy spread of a beam through materials by integrating the scattering formulae through thick materials as the beam slows down, adding the rms transverse scattering and longitudinal straggling during the process. A beam of given energy, emittance and betatron amplitude is integrated through a sequence of materials. Along the way, the beam characteristics are listed. The beam distribution is assumed to be gaussian, as is the scattering. The rms beam size is the profile through the center of the distribution: the rms of the beam integrated through the transverse plane is $\sqrt{2}$ smaller.

In the following example, a 250 MeV proton beam with zero initial size is presented to elements at the end of the nozzle. A multiwire monitor (harp) is represented by 0.005 cm of graphite, followed by 110 cm of vacuum and a SEM with an equivalent thickness of 0.0125 cm of aluminum. The Kapton exit window is represented by 0.0127 cm of polyethylene which is coupled directly to a 170 cm long helium bag, ending in an ion chamber equivalent to 0.0381 cm of polyethylene. The last path is 50 cm of air.

The program lists the running path length sum along the beamline, the energy after each element, the rms beam sizes, and the betatron parameters. The first table lists the element definitions in the beam line:

i	Thickness	Strength	Foilnum	Name	(Medium)
1	0.0050	0.0000	6	Wires	Graphite
2	110.0000	0.0000	0		Vacuum
3	0.0125	0.0000	13	SEM	Aluminum
4	0.0127	0.0000	110	Window	Polyethylene
5	170.0000	0.0000	2	Gas	Helium Gas
6	0.0381	0.0000	110	IC#1	Polyethylene
7	50.0000	0.0000	105	Air	Air

The beam parameters for an initial 250 MeV beam are listed below:

name	dL (cm)	sumL (cm)	KE (MeV/n)	KErms (MeV/n)	xrms (cm)	x'rms (mrad)	emitrms (pi cm-mr)
		0.00	250.0000	0.000	0.000	0.00	0.000
Wires	0.0050	0.00	249.9610	0.030	0.000	0.63	0.000
	110.0000	110.00	249.9610	0.030	0.069	0.63	0.000
SEM	0.0125	110.02	249.8568	0.059	0.069	1.66	0.107
Window	0.0127	110.03	249.8080	0.067	0.069	1.73	0.112
Gas	170.0000	280.03	249.6942	0.083	0.331	1.84	0.169
IC#1	0.0381	280.07	249.5478	0.100	0.331	2.01	0.319
Air	50.0000	330.07	249.3208	0.123	0.425	2.65	0.726

For an initial beam energy of 150 MeV:

name	dL (cm)	sumL (cm)	KE (MeV/n)	KErms (MeV/n)	xrms (cm)	x'rms (mrad)	emitrms (pi cm-mr)
		0.00	150.0000	0.000	0.000	0.00	0.000
Wires	0.0050	0.00	149.9458	0.030	0.000	1.05	0.000
	110.0000	110.00	149.9458	0.030	0.116	1.05	0.000
SEM	0.0125	110.02	149.8014	0.059	0.116	2.77	0.296
Window	0.0127	110.03	149.7332	0.067	0.116	2.88	0.310
Gas	170.0000	280.03	149.5741	0.083	0.552	3.06	0.471
IC#1	0.0381	280.07	149.3695	0.100	0.552	3.36	0.890
Air	50.0000	330.07	149.0530	0.123	0.709	4.43	2.025

For an initial beam energy of 70 MeV:

name	dL (cm)	sumL (cm)	KE (MeV/n)	KErms (MeV/n)	xrms (cm)	x'rms (mrad)	emitrms (pi cm-mr)
		0.00	70.0000	0.000	0.000	0.00	0.000
Wires	0.0050	0.00	69.9049	0.030	0.000	2.25	0.000
	110.0000	110.00	69.9049	0.030	0.248	2.25	0.000
SEM	0.0125	110.02	69.6532	0.059	0.248	5.95	1.366
Window	0.0127	110.03	69.5327	0.067	0.248	6.19	1.431
Gas	170.0000	280.03	69.2502	0.083	1.188	6.60	2.181
IC#1	0.0381	280.07	68.8867	0.101	1.189	7.25	4.143
Air	50.0000	330.07	68.3252	0.124	1.528	9.61	9.488

In the three cases, the final rms beam size σ_x is:

Energy (MeV)	σ_x (cm)	Emittance (π cm-mrad)
250	0.425	0.726
150	0.709	2.025
70	1.528	9.488

Even the small amount of material in the line materially increases the emittance of the beam, resulting in a large spot size, even with an (unrealistically) zero emittance initial beam phase space area. The expected emittance from the accelerator itself will be in

the range of $0.2\text{--}0.5 \pi$ cm-mrad, rms unnormalized. We have not yet considered monitors upstream the transport system nearer the accelerator that would be used for beam extraction feedback.

Because the presence of monitors in the beam, and the vacuum window and the scattering in air, the size of even the most optimally focused scanning spot will be larger than the 0.3 rms cm goal. Safety dictates that the vacuum window not be located too close to the patient, and a helium bag may be necessary over the last part of the beam line to reduce the scattering over the significant amount caused in air.

Analysis of a Strawman Beam Transport and Gantry

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2 December 1992

A. Introduction

To aid in the design of the beam transport system from the accelerator to the various beam preparation devices (gantries, stationary beam lines), a strawman design is presented and analyzed. This design contains a complete design example of the ion optics of a typical gantry-based beam delivery system. The design is modular in nature and can be easily expanded to provide beam to several treatment areas. This design has several deficiencies that are discussed, and a sensitivity analysis of the transport system including errors in positioning and excitation of the magnetic elements, and the sensitivity to the characteristics of the beam from the accelerator.

B. A Design Example

A strawman design for a gantry-based beam delivery system has been worked out. It includes all magnetic elements from the extraction Lambertson magnet in the accelerator ring all the way to the isocenter, but omits the scanning system, which is assumed to follow the last magnet in the gantry.

The beamline configuration is modular, with the modules clearly identifiable and analyzable. The modular design allows changes in the configuration, more gantries to be added, and uniformity and economy of implementation.

The beamline was design using the interactive LATTICE program to construct the first-order optics and carry out the sensitivity analysis and graphical displays, and TRANSPORT to investigate the third-order optics and the effects of beam and magnet displacement errors. LATTICE automatically generates an input file to TRANSPORT, eliminating error in translation and allowing all the design work to be conveniently carried out with LATTICE.

Figure 1 shows the three-dimensional configuration of the system with the gantry in the upright configuration. Figure 2 shows the gantry tilted 45° clockwise (not further analyzed here).

Figure 3 shows the configuration and names of the elements, presented in a two-dimensional configuration, with the gantry unrolled. Figure 4 shows the beam envelope for the locally horizontal (top) and vertical (bottom) planes, along with the horizontal and vertical dispersion vectors (dotted lines).

The energy from the accelerator may be switched on a pulse-by-pulse basis. The entire beam transport system must track the energy changes, with little time allowed for verification of the new tune. Therefore, the beam transport system should be fully

achromatic, to minimize the sensitivity of beam position at the isocenter to energy tracking errors.

- (1) **Extraction System.** The accelerator extraction system which consists of a Lambertson magnet deflecting the extracted beam vertically down and away from the synchrotron magnets. A following magnet of equal upward bend returns the beam to the horizontal. If this magnet is turned off, the beam is safely transported to a beam dump buried in the floor.
- (2) **First Matching Element.** A quadrupole doublet follows which matches the beam from the accelerator to the next part of the beam line. This doublet focuses the beam from the accelerator into the periodic transport system.
- (3) **Long FODO Lattice.** The beam is then transported along a periodic FODO lattice, the "spine" of the transport system, from which deflecting magnets bend the beam into the various caves where the gantries and fixed beam lines are implemented.

The optics are telescopic: i.e. the transfer matrix to selected points along the line is ± 1 (multiples of π phase advance). The beam parameters at the entrance are reproduced at these "magic" locations, where "tap-offs", or deflection magnets, can be located.

- (4) **Deflecting Magnet.** The beam is tapped off the periodic transport system section and sent to a treatment cave by an achromatic 90° bend system. Achromaticity is required as the entire system must be retunable to a new energy on a pulse-by-pulse basis. As it is likely that errors will occur in the output energy of the synchrotron or in the resetting of the magnet fields in the transport system, the tight beam positioning requirements at the isocenter most likely require a fully achromatic system, even though the momentum spread from the accelerator is low.
- (5) **Round Beam Generator.** A matching section, partially incorporated into previous section, and partially isolated, establish a beam with rotational symmetry at the rotation reference point for the gantry. We set $\beta_x = \beta_y$, $\alpha_x = \alpha_y$, $\eta_x = \eta_y = 0$ and $\eta'_x = \eta'_y = 0$ at the point of rotation for the gantry. If the emittances in both transverse planes are equal, $\epsilon_x = \epsilon_y$, the beam emittance and betatron parameters will be preserved during gantry rotation.
- (6) **Gantry.** A Koehler-style corkscrew gantry is used in this example. The beam enters through a four-quadrupole matching section that takes the initially round beam to the first of two 45° dipoles, and then to two 135° dipoles in the perpendicular plane. Two sets of symmetric triplets (one set split) are located between each pair of dipoles to render the gantry fully achromatic.

C. Shortcomings of This Design

The strawman design has several known defects, introduced to illustrate a design at the beginning of the conceptualization process. These shortcomings are pointed out below, and it is the expected of the vendor to consider and correct these shortcomings and to produce a competitive, efficient and economical final design.

- (1) **Extraction System.** The beam is launched into the first element, the Lamberton, by the extraction system of the synchrotron ring with the following ideal characteristics:

$$\begin{aligned}\beta_x &= \beta_y = 1 \text{ meter} \\ \alpha_x &= \alpha_y = 0 \\ \eta_x &= \eta_y = 0 \\ \eta'_x &= \eta'_y = 0 \\ \pi \epsilon_x &= \pi \epsilon_y = 1 \text{ } \pi \text{ cm-mrad, rms} \\ \Delta p/p &= 0\end{aligned}$$

In actuality, the beam launched into the transport system from the accelerator will not have such ideal characteristics. The emittances in the two planes will in general differ, which will result in changing beam characteristics at the exit of the gantry as it is rotated, as the phase planes mix at the rotation point.

A slight non-zero vertical dispersion results from the translation of these two magnets which is uncompensated for in the rest of the beam line. This is a significant albeit minor defect in this section of the beam line.

- (2) **First Matching Element.** The betatron parameters of the beam from the synchrotron are not fully predictable and will vary with energy. An improved method must be provided to measure and accommodate variations in the beam parameters as they are launched toward the rest of the transport system. Ideally, the beam can be focused to a standard set of betatron parameters, and the emittances in both planes be made equal by judiciously located slits along the FODO lattice. Thus the tuning of the downstream sections may be standardized. More individual focusing quadrupoles at the front of the FODO lattice may be required to accommodate a range of beam initial conditions.

The position, angle and energy of the beam from the accelerator may vary during the pulse or between pulses. Adequate monitoring must be provided to measure the beam characteristics from the accelerator and to verify that it is launched along the FODO lattice correctly. Active feedback compensation requires real-time measurement of the beam characteristics, but this is somewhat incompatible with the emittance blow-up associated with in-beam monitors. Monitoring electrons from residual gas ionization may be difficult and expensive, and is sensitive to contamination from vacuum accidents. An adequate monitoring system that does not adversely affect the beam characteristics must be devised.

- (3) **Long FODO Lattice.** The beam from the accelerator extraction septum is focused into a long periodic FODO structure. At some point, a 90° achromatic deflection system turns the beam toward the gantry. If the first dipole in the deflection system is turned off, the beam continues along an extension of the periodic FODO structure to similar systems downstream.

The deflecting magnets along this spine, each servicing another cave, ideally would be located at multiples of π phase advance along the periodic structure, so the beam has the same betatron parameters at each tapping-off place. This allows

each gantry or beam line to have beam of identical characteristics no matter where on the spine it is siphoned off. In this example, the spine, consisting of 8 quadrupoles of equal and alternating strength, do not have a π phase advance from beginning to end, but this can be easily implemented.

A FODO lattice requires the least quadrupole excitation but the largest apertures. Other lattices, such as a FDO configuration may provide better performance at the expense of higher power requirements.

All quadrupoles along the FODO lattice may be tied in series, simplifying tuning, but establishing the required tune (phase advance) may be difficult in practice. Deflecting the beam at some upstream point and monitoring and zeroing the deflection at points located 180° downstream may be one way of properly setting the quadrupole strengths.

- (4) **Deflecting Magnet.** The beam is tapped off of the FODO lattice by an achromatic deflecting system, here consisting of two 45° magnets surrounding a quadrupole triplet. The large deflection angle is accompanied by strong focusing in the bending plane of the magnets, which complicates the design of the optics, as the beam tends to form a small waist at at least one point in the system. If the gantries are arranged so the beam is deflected at less than a 90° angle from the backbone, the optics design may be improved.
- (5) **Round Beam Generator.** To preserve the beam characteristics as the gantry is rotated, the beam must be round (with equal divergences) at the point of rotation. Preparation of a round beam is difficult, and depends on equal emittances in both transverse phase planes, and fully achromatic beam transport upstream. Verification of the betatron parameters will also be different.

In this design example, one quadrupole follows the 90° bend, and along with the triplet in the bend, forms the required beam. This system is not very versatile, and depends on the correct beam configuration at the entrance of the 90° bend section.

The round beam after the rotation point is focused by four quadrupoles (which rotate with the gantry) into the first 45° bending magnet of the gantry. The space required in this example between the exit of the upstream 90° deflecting system and the first 45° of the gantry is quite long, and may have an adverse effect on the design of the building. A better design would shorten this distance and provide more flexibility to accommodate varying beam parameters from the accelerator.

- (6) **Gantry.** The beam from the 90° bend is rendered round upstream of the point of rotation into the gantry structure. The gantry brings the beam achromatically back to the isocenter, which is at the center of rotation of the gantry.

In any design that uses dipoles with large deflection angles, strong focusing in one or both transverse phase planes that necessarily accompanies the large bend angles complicates the optical design of the gantry, particularly when the design must also be achromatic.

A solution is given which has a large sensitivity to tuning errors, due to the fast rate of betatron phase advance through the gantry. This is probably unavoidable,

as the tuning range must be sufficiently flexible to allow the beam at the isocenter to be tuned over a wide range of sizes, from the smallest pencil beam to large spread beams.

The beam at the isocenter (exit of the beam line) has a nominally a $\sigma_x = \sigma_y = 0.5$ cm rms size, with almost zero dispersion and non-zero envelope slopes. This is a representative beam used in scanning, with a two-dimensional magnetic deflecting system (not included in this analysis) located immediately after the last gantry magnet. The beam optics through the gantry must be versatile enough to allow a large beam to be presented at the isocenter, and to allow a beam to be focused on scatters in lieu of scanning.

D. Sensitivity Analysis

The sensitivity of the beam parameters at the isocenter for the particular tune given is calculated for a few sample perturbations.

Third-order TRANSPORT calculations are carried out for initial beam offset and angle errors and for errors in the excitation and alignment in selected magnets.

Input Beam Offset.

The position and size of the beam at the isocenter as a function of the input beam offset and angle is calculated, using third order optics. This is an example of a higher-order perturbation analysis that is to be applied to errors in initial beam offsets and matching parameters, and in positioning errors of magnetic elements all along the beam line. This example will illustrate only the initial beam offset case.

Figures 5a-d show the final beam offset and rms size as a function of initial position offset and angle for both the x- and y-planes. Note that there is a residual offset in the beam at the isocenter in both planes even with no initial offset or angle. This results from the third-order analysis where the initial beam ellipse is distorted by the higher-order transport errors and the center of gravity of the final distribution lies off the axis.

By observing the sensitivity of the final beam offset and size, the offset and angle of the initial beam can be determined, setting the constraints on the accuracy of the resonant extraction system.

Beam Line Acceptance.

The geometric phase space acceptance of the beam line is determined by transforming (in first order in this case) the apertures of all the magnetic elements to the beginning of the beam line and determining the phase space volume of the limiting apertures.

In this case, all quadrupoles are given a round aperture radius of 2 cm, except those quadrupoles in the round beam matcher and in the final triplet of the gantry, which have an aperture radius of 5 cm. The dipoles have a half-gap of 2 cm.

Figures 6a-f show the geometric acceptance in the x and y planes for beam momentum offsets of -0.5%, 0% and +0.5%. The nominal input beam ellipse with an envelope representing a phase space area of 1π cm-mrad is also shown on each figure. The x-

plane acceptance varies slowly with momentum, but the y-plane acceptance is seen to start to pinch off at the $\pm 0.5\%$ momentum offsets due to the aperture limitation in some of the elements.

Although the energy spread from the accelerator is specified as being less than $\pm 0.1\%$ ($\Delta p/p \sim 0.05\%$), tracking errors in the transport system may cause beam offsets at critical points, reducing efficiency and causing local activation hotspots. The apertures in the beam line should be sized to account for anticipated mistracking of the transport system as it tracks the accelerator energy.

Quadrupole Tuning Errors The rate of phase advance along this example beam transport system varies considerably, due in part in accommodating the strong focusing which accompanies the large bend angles in the dipoles. Some quadrupoles are at large β points, and strongly affect the final beam parameters.

The sensitivity of eight quadrupoles is shown in the following table. Six quadrupoles, xqff, xqdd, q1, q2, q3 and q4 in pairs, achromatize the three major bends in the system: the 90° bend from the backbone, and the 90° and 270° bends in the gantry. Two quadrupoles, qa and qb, are part of the round beam matcher at the entrance of the gantry and are chosen as they are at the highest β_x and β_y points in the system.

The beam sizes σ_x and σ_y , along with the dispersion in the two planes, η_x and η_y are given when the strength of each quadrupole, individually, is raised by 1%. Parameters which seem particularly sensitive are highlighted. The first line is the unperturbed third-order calculation of the beam size and dispersion functions at the isocenter. The initial dispersion in the y-plane is due to the uncompensated dispersion due to the extraction chicane.

Quad	σ_x (cm)	σ_y (cm)	η_x (m)	η_y (m)
(none)	0.487	0.500	0.000	-0.256
xqff	0.480	0.488	-0.020	-0.249
xqdd	0.490	0.518	0.005	-0.265
q1	0.507	0.495	0.016	-0.253
q2	0.428	0.507	-0.066	-0.259
q3	0.441	0.502	0.000	-0.308
q4	0.500	0.502	0.000	-0.161
qa	0.372	0.573	0.000	-0.276
qb	0.553	0.561	0.000	-0.216

The setting accuracy of the quadrupoles will be determined by such a sensitivity analysis and the allowable variations of the size and dispersion sensitivity of the beam parameters at the isocenter.

Appendix A - LATTICE input file

```

* Prototype beam transport system and gantry
b 2.43000 1.00000 1.00000 0.00000
t 1.00000 0.00000 1.00000 0.00000 0.00000 0.00000 0.00000 0.00000
sc 5.00000 5.00000 10.00000 10.00000
e
lamb B 0.0 0.500000 -0.800000 0.000000 0.000000 0.000000
xd1 d 0.0 0.500000 0.000000 0.000000 0.000000 0.000000
xup B 0.0 0.500000 0.800000 0.000000 0.000000 0.000000
xd2 d 0.0 1.000000 0.000000 0.000000 0.000000 0.000000
xq1 q 0.0 0.300000 7.000000 0.000000 0.020000 0.020000
xd3 d 0.0 0.300000 0.000000 0.000000 0.000000 0.000000
xq2 q 0.0 0.300000 -7.000000 0.000000 0.020000 0.020000
xd4 d 0.0 2.000000 0.000000 0.000000 0.000000 0.000000
xqf q 0.0 0.300000 2.300000 0.000000 0.020000 0.020000
xqd q 0.0 0.300000 -2.300000 0.000000 0.020000 0.020000
xd5 d 2.1 0.004219 0.000000 0.000000 0.000000 0.000000
xb45 b 0.0 1.272300 1.500000 0.000000 0.000000 0.000000
xd6 d 0.0 0.300000 0.000000 0.000000 0.000000 0.000000
xd7 d 3.1 0.191687 0.000000 0.000000 0.000000 0.000000
xqdd q 5.2 0.300000 -5.256900 0.000000 0.020000 0.020000
xqff q 4.2 0.300000 7.496576 0.000000 0.020000 0.020000
xq3 q 1.2 0.250000 1.657384 0.000000 0.020000 0.000000
xd8 d 0.0 0.200000 0.000000 0.000000 0.000000 0.000000
l d 0.0 2.900000 0.000000 0.000000 0.000000 0.000000
qa q 1.2 0.300000 10.883532 0.000000 0.020000 0.020000
s0 d 0.0 1.000000 0.000000 0.000000 0.000000 0.000000
qb q 2.2 0.300000 -10.218803 0.000000 0.020000 0.020000
l0 d 0.0 0.200000 0.000000 0.000000 0.000000 0.000000
d1 b 0.0 0.600000 1.590400 0.500000 0.020000 0.000000
l1 d 0.0 0.200000 0.000000 0.000000 0.000000 0.000000
q1 q 0.0 0.300000 -4.420400 0.000000 0.020000 0.020000
s1 d 0.0 0.050000 0.000000 0.000000 0.000000 0.000000
q2 q 0.0 0.300000 8.748000 0.000000 0.020000 0.020000
l2 d 0.0 0.400000 0.000000 0.000000 0.000000 0.000000
l3 d 0.0 0.200000 0.000000 0.000000 0.000000 0.000000
d3 B 0.0 0.900000 1.590400 0.500000 0.000000 0.020000
q3 q 0.0 0.500000 8.753200 0.000000 0.020000 0.020000
s2 d 0.0 0.050000 0.000000 0.000000 0.000000 0.000000
q4 q 0.0 0.250000 -12.337400 0.000000 0.020000 0.020000
l5 d 0.0 0.200000 0.000000 0.000000 0.000000 0.000000
l6 d 0.0 3.200000 0.000000 0.000000 0.000000 0.000000
l4 d 0.0 0.750000 0.000000 0.000000 0.000000 0.000000
qc q 3.2 0.300000 2.384439 0.000000 0.020000 0.020000
qd q 4.2 0.300000 -0.171634 0.000000 0.020000 0.020000
s3 d 0.0 0.150000 0.000000 0.000000 0.000000 0.000000
rot r 0.0 0.000000 0.000000 0.000000 0.000000 0.000000
end
l
lamb xd1 xup xd2 xq1 xd3 xq2
xd4 xqf xd4 xqd xd4 xqf xd4
xqd xd4 xqf xd4 xqd xd4 xqf
xd4 xqd xd8 xb45 xd6 xqdd xd7

```

xqff	xqff	xd7	xqdd	xd6	xb45	xd5
xq3	rot	1	qd	s3	qc	s0
qb	s3	qa	10	d1	d1	11
q1	s1	q2	12	12	q2	s1
q1	11	d1	d1	13	d3	d3
d3	d3	14	q3	s2	q4	q4
s2	q3	14	d3	d3	d3	d3
15	16					

end
p 1

Appendix B - Transport input file

```

0
(Input file t+g translated to Transport format by lat2x.)
13.0 2.0;
1.0 0.316 3.162 0.316 3.162 0.000 0.000 0.72849 'beam';
-17.0 'ord2';
17.0 3.0 'ord3';
12.0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 'corr';
20.0 -90.0 'zrot';
4.0 0.5000 8.0000 0.000 'lamb';
20.0 90.0 'zrot';
3.0 0.5000 'xd1 ';
20.0 90.0 'zrot';
4.0 0.5000 8.0000 0.000 'xup ';
20.0 -90.0 'zrot';
3.0 1.0000 'xd2 ';
5.0 0.3000 7.0000 10.0 'xq1 ';
3.0 0.3000 'xd3 ';
5.0 0.3000 -7.0000 10.0 'xq2 ';
3.0 2.0000 'xd4 ';
5.0 0.3000 2.3000 10.0 'xqf ';
3.0 2.0000 'xd4 ';
5.0 0.3000 -2.3000 10.0 'xqd ';
3.0 2.0000 'xd4 ';
5.0 0.3000 2.3000 10.0 'xqf ';
3.0 2.0000 'xd4 ';
5.0 0.3000 -2.3000 10.0 'xqd ';
3.0 2.0000 'xd4 ';
5.0 0.3000 2.3000 10.0 'xqf ';
3.0 2.0000 'xd4 ';
5.0 0.3000 -2.3000 10.0 'xqd ';
3.0 2.0000 'xd4 ';
5.0 0.3000 2.3000 10.0 'xqf ';
3.0 2.0000 'xd4 ';
5.0 0.3000 -2.3000 10.0 'xqd ';
3.0 0.2000 'xd8 ';
4.0 1.2723 15.0000 0.000 'xb45';
3.0 0.3000 'xd6 ';
5.0 0.3000 -5.2569 10.0 'xqdd';

```



```

3.0 0.1917 'xd7 ' ;
5.0 0.3000 7.4966 10.0 'xqff' ;
5.0 0.3000 7.4966 10.0 'xqff' ;
3.0 0.1917 'xd7 ' ;
5.0 0.3000 -5.2569 10.0 'xqdd' ;
3.0 0.3000 'xd6 ' ;
4.0 1.2723 15.0000 0.000 'xb45' ;
3.0 0.0042 'xd5 ' ;
5.0 0.2500 1.6574 10.0 'xq3 ' ;
20.0 0.000 'rot ' ;
3.0 2.9000 'l ' ;
5.0 0.3000 -0.1716 10.0 'qd ' ;
3.0 0.1500 's3 ' ;
5.0 0.3000 2.3844 10.0 'qc ' ;
3.0 1.0000 's0 ' ;
5.0 0.3000 -10.2188 10.0 'qb ' ;
3.0 0.1500 's3 ' ;
5.0 0.3000 10.8835 10.0 'qa ' ;
3.0 0.2000 'l0 ' ;
4.0 0.6000 15.9040 0.500 'd1 ' ;
4.0 0.6000 15.9040 0.500 'd1 ' ;
3.0 0.2000 'l1 ' ;
5.0 0.3000 -4.4204 10.0 'q1 ' ;
3.0 0.0500 's1 ' ;
5.0 0.3000 8.7480 10.0 'q2 ' ;
3.0 0.4000 'l2 ' ;
3.0 0.4000 'l2 ' ;
5.0 0.3000 8.7480 10.0 'q2 ' ;
3.0 0.0500 's1 ' ;
5.0 0.3000 -4.4204 10.0 'q1 ' ;
3.0 0.2000 'l1 ' ;
4.0 0.6000 15.9040 0.500 'd1 ' ;
4.0 0.6000 15.9040 0.500 'd1 ' ;
3.0 0.2000 'l3 ' ;
20.0 90.0 'zrot' ;
4.0 0.9000 15.9040 0.500 'd3 ' ;
4.0 0.9000 15.9040 0.500 'd3 ' ;
4.0 0.9000 15.9040 0.500 'd3 ' ;
4.0 0.9000 15.9040 0.500 'd3 ' ;
20.0 -90.0 'zrot' ;
3.0 0.7500 'l4 ' ;
5.0 0.5000 8.7532 10.0 'q3 ' ;
3.0 0.0500 's2 ' ;
5.0 0.2500 -12.3374 10.0 'q4 ' ;
5.0 0.2500 -12.3374 10.0 'q4 ' ;
3.0 0.0500 's2 ' ;
5.0 0.5000 8.7532 10.0 'q3 ' ;
3.0 0.7500 'l4 ' ;
20.0 90.0 'zrot' ;
4.0 0.9000 15.9040 0.500 'd3 ' ;
4.0 0.9000 15.9040 0.500 'd3 ' ;
4.0 0.9000 15.9040 0.500 'd3 ' ;
4.0 0.9000 15.9040 0.500 'd3 ' ;
20.0 -90.0 'zrot' ;
3.0 0.2000 'l5 ' ;
3.0 3.2000 'l6 ' ;

```

(Print the beam sigma matrix, and the total R1 transformation matrix.)

13.0 1.0 ;

13.0 4.0 ;

(Remove the minus sign to give a geometric survey, move to top of data

-13.0 12.0 'xyz ';

SENTINEL

SENTINEL

Figure 1. Isometric views of gantry in 90° position.

Figure 2. Isometric views of gantry in 45° position.

Example Beamline

Figure 4. Beam line envelope profiles for 1π cm-mrad emittance.

Figure 5a. X-beam size an offset for initial x-displacement error.

Figure 5b. X-beam size an offset for initial x-angular error.

Figure 5c. Y-beam size an offset for initial y-displacement error.

Figure 5d. Y-beam size an offset for initial y-angular error.

Figure 6a. X-acceptance with $\Delta p/p = -0.5\%$. Figure 6b. X-acceptance with $\Delta p/p = 0.0\%$.

Figure 6c. X-acceptance with $\Delta p/p = +0.5\%$. Figure 6d. Y-acceptance with $\Delta p/p = -0.5\%$.

Figure 6e. Y-acceptance with $\Delta p/p = 0.0\%$. Figure 6f. Y-acceptance with $\Delta p/p = +0.5\%$.