# Code Of Practice for Proton Therapy Systems: Developing Clinical Specifications and a Purchase Agreement for a Proton Therapy System

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## Key Components of a Proton Therapy Project Plan

- Request for Proposals – What you want.
- Business Plan – What you plan to do with it.

## Business Plan

- Patient Load
- Equipment Requirements
- Capital costs
- Hours of Operation
- Staffing Requirements
- Program Ramp-up
- Operating Expenses
- Operating Revenues

## Request for Proposals

- Equipment Specifications
- Equipment Maintenance
- Conditions for Bidding and Proposals
- Terms and Conditions
- Project Management
- Risk Management
- Regulatory Issues
- Interfacing of Equipment with Building
- Vendor Profile and Business

## Request for Proposals

Specify Equipment Needs:

- Proton Therapy
- Heavy Ions
- Other Ions
- Oncology Information System
- Treatment Planning
- Imaging Equipment: Simulation and On-Board
- Integration of Equipment from different Vendors

## Request for Proposals

- At Penn RFP developed for a completely integrated radiation oncology department.
- One primary supplier for all equipment with that supplier responsible for all installation and connectivity issues.
- Proton specifications based in part on Lawrence Berkeley Laboratory Document (LBL-33749).

## Particle Issues

## Protons vs $^{12}C$

Proton Pros

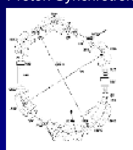
- Protons are reimbursable
- Protons are suitable for treating practically all disease sites
- Proton equipment is less expensive

$^{12}C$ Pros

- $^{12}C$ are high LET particles
- $^{12}C$ accelerator may accelerate protons, $^{3}He$, $^{4}He$ and other light ions
- More research opportunities

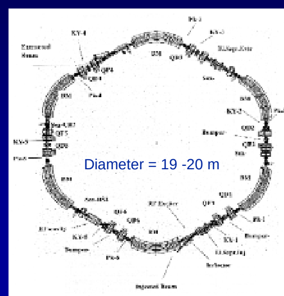
## Protons vs $^{12}C$ and Protons

Proton Synchrotron



Diameter = 7- 8 m

Proton/$^{12}C$ Synchrotron




## Protons vs $^{12}C$

- Can Proton Business Plan Support $^{12}C$ research until it is reimbursable?
- What is risk factor with $^{12}C$?

## Equipment Issues

## Equipment Issues

1. Cyclotron vs Synchrotron
2. Scattering vs Scanning

## Cyclotron vs Synchrotron
## Energy

Cyclotron

- Fixed output energy.
- Energy variation requires post acceleration energy selector. Activation “problem”

Synchrotron

- Energy variable from pulse to pulse.

## Cyclotron vs Synchrotron
## Intensity

Cyclotron

- Continuous beam current 10µA or more.
- Stable beam output. Can be precisely controlled

Synchrotron

- Maximum beam intensity ~ 2.4 x $10^{12}$ pulses/min (For scattering at the limit for 2 Gy/min/liter)
- Pulsed beam structure. Spill structure “unstable” (RF-driven /RF knock out extraction essential)

## Cyclotron vs Synchrotron

- For a cyclotron beam intensity and stability are an advantage for scattered and scanned beams.
- For a synchrotron pulse to pulse energy variation is a potential advantage for scanned beams

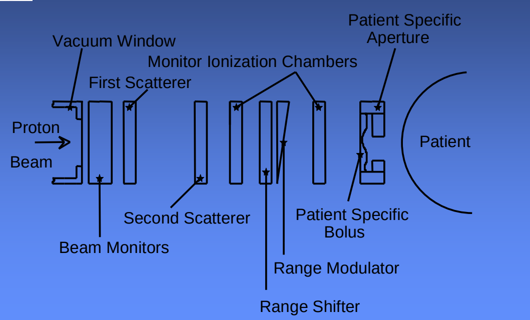
## Scattering vs Scanning
### Proton Beam Delivery

- Beam Delivery Systems – Nozzle

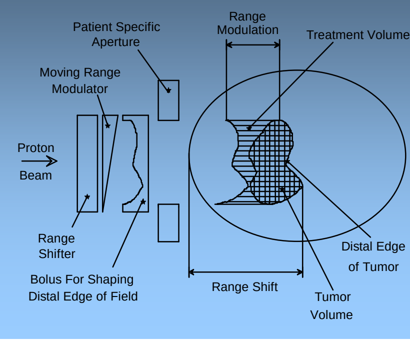
  - scattering systems

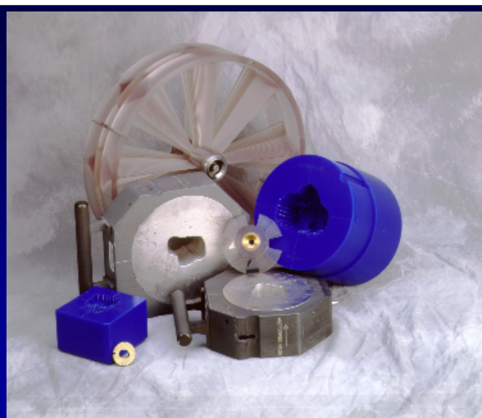
  - scanning systems

## Schematic of Beam Delivery Nozzle Scattering




## Patient Specific Beam Modifiers Scattering



Slide courtesy of LLUMC

## Double Scattering and Large Field Sizes

- In double scattering field size is a limitation.
- As field diameter increases beyond ~ 20–25 cm range deceases to less than ~ 28 cm.

## Uniform Scanning

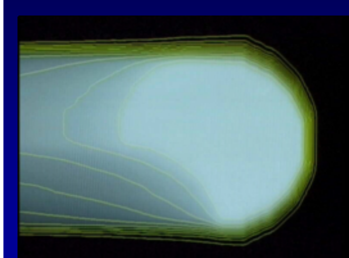
- Uses a large spot ~ 5 cm diameter.
- Uses modulation to spread out the Bragg peak.
- Uses an aperture.
- Spot is scanned across the fields.
- An efficient method for treating large fields and without degrading range.

## Pencil Beam Scanning System

- With variable energy beam the problem of matching the high intensity region of the beam to the proximal edge of the tumor can be overcome.
- A narrow beam with a narrow Bragg peak is scanned over the tumor area as the energy of the beam is varied.
- “Voxels” of dose are painted throughout the tumor volume.

## Spot scanning - The principle

**The dynamic application of scanned and modulated proton pencil beams**



A full set, with a homogenous dose conformed distally *and* proximally

Images courtesy of E Pedroni and T Lomax, PSI

## Scattering vs Scanning

- Scattering – no problem with organ motion.
- Scanning requires gating to overcome organ motion problems.
- Scanning – better conformation to target volume.
- Scanning - patient safety is a bigger problem than with scattering.
- Scanning – suitable for large volumes.
- Scanning – allows for IMPT

## Scattering vs Scanning

- Probably need both scattering and scanning for protons in the immediate future.
- Scanned beams offer better conformation and are more efficient and will probably be the long term solution.
- Some scattered beams may always be necessary to overcome motion problems

## Commercial Equipment: Multi-room Systems

| | |
|---|---|
| • Accel | 250MeV superconducting cyclotron |
| • Hitachi | 270 MeV proton synchrotron |
| • IBA | 230MeV cyclotron |
| • Mitsubishi | 235 MeV proton synchrotron |
| • Mitsubishi* | 320MeV/u synchrotron (20 cm – $^{12}C$) |
| • Optivus | 250 MeV proton synchrotron |
| • ProTom | 330 MeV/u proton synchrotron |
| • Siemens * | 430 MeV/u synchrotron (30 cm – $^{12}C$) |

* Proton and $^{12}C$

## Commercially Available Equipment: Single Room Systems

| | |
|---|---|
| • Still River | 250 MeV gantry mounted compact superconducting synchrocyclotron. In production. |
| • Tomotherapy | 250 MeV Dielectric Wall Accelerator. Compact linear accelerator. Feasibility testing. |

## Do you need an RFP?

- When buying an expensive multi-room system ($60-100M+) the customer want to customize the system to their specific needs.
- Proton systems have not yet reached “maturity.
- Scattering systems are quite advanced.
- Scanning systems have only just been introduced commercially and need further development.
- Integration of Oncology Information System, Record and Verify, and Treatment Planning Systems needs further improvement.

## Penn Experience

- Penn had some unique requirements which were incorporated in two the contract as development agreements. These were;
- An MLC for scattered and uniform scanned beams.
- The inclusion of CBCT on the gantry.
- Another development agreement covered PBS which was under development and not FDA approved

## Will things change?

- Yes, of course. As products mature, vendors will offer better defined systems with options.
- This may still be a few years away for large multi-room systems.

## Single Room Systems

- These systems are designed to be less expensive (estimate: ~$20M).
- There may be limitations to the beam delivery system – less options.
- Vendors may offer systems with well defined specifications and few options to contain costs.

## Request for Proposals and Contracts

## Request for Proposals

- Specifications
- Installation, Acceptance and Commissioning
- System Maintenance
- Conditions for Bidding and Proposals
- Terms and Conditions
- Project Management
- Risk Management
- Regulatory Issues
- Interfacing of Equipment with Building
- Vendor Profile and Business

## Request for Proposals

- The RFP may be sent to a relatively large number of vendors.
- Evaluation of the responses to the RFP is a team effort:

  Physicists, Physicians, Administrators, Architects, Facility Management.
- The Medical Physicist does not needed to be involved in all aspects of this evaluation.
- Primary concerns for the physicist should be equipment specifications, acceptance, commissioning and maintenance. Radiation safety related regulatory issues. The building interface and system installation may be another important concern.

## Development of Specifications

- Resources development of specifications:
- Lawrence Berkeley Laboratory Document, 1993 (LBL-33749) : "Performance Specifications for Proton Medical Facility," W.T. Chu *et al.* remains the major resource. Available on-line at: http://www.osti.gov/bridge//product.biblio.jsp?query_id=0&page=0&osti_id=10163935
- AAPM Task Group 183: "Nomenclature, Specifications, Safety Requirements and Acceptance Testing for Proton therapy Systems." Chair: Richard Maughan.

  Anticipated publication within 18-24 months.

## Development of Specifications

- In writing specifications it is necessary to understand that physical limitations may result in an interplay between various specifications. For example:
- In double scattering increasing the field size reduces the maximum range.
- In PBS reducing the minimizing spot size to reduce penumbra may increase irradiation time for large fields unacceptably.

## Specification Outline

1. Proton Therapy Machine and Beam Line

1.1 Energy
1.2 Intensity
1.3 Monitoring
1.4 Beam switching time

## Specification Outline

2. Nozzle

2.1 Passive scattering nozzle

2.2 Scanning nozzle

## Specification Outline

2.1 Passive scattering nozzle
2.1.1 Field size
2.1.2 Beam uniformity
2.1.3 Beam size and penumbra
2.1.4 Beam position and stability
2.1.5 Modulator wheel/ridge filter
2.1.6 Collimation
2.1.7 Compensators
2.1.8 Dose Monnitoring
2.1.9 Interlocks

## Specification Outline

2.2 Scanning Nozzle
2.2.1 Field size
2.2.2 Beam uniformity
2.2.3 Beam size and penumbra
2.2.4 Beam position and stability
2.2.5 Clearance to isocenter
2.2.6 Dose Monitoring
2.2.7 Interlocks

## Specification Outline

3. Treatment Room

3.1 Localization system – On-Board Imaging Systems

3.2 Patient couch – 6 Degrees of Freedom.

3.3 Gantry

## Specification Outline

4. Eye Beam

4.1 Eye beam nozzle

4.2 Localization system

4.3 Patient chair

## Specification Outline

5. Beam Gating

6. Integrated Patient Information, Treatment and Accelerator control System

6.1 Record and verify

6.2 Control system

## Specification Outline

7. Treatment Planning

7.1 Computer simulation of proton beam parameters.

7.2 Transfer of parameters to record and verify system.

7.3 Export files to computer controlled machining device for compensator/aperture manufacture.

7.4 Monitor unit calculation.

7.5 Export in DICOM-RT or ASCII format for non DICOM-RT proton specific information.

7.6 Combined photon, electron and proton plans with composite isodose plots and DVHs.

## Specification Outline

8. Simulation Imaging equipment

8.1 CT simulators

8.2 PET/CT

8.3 MRI

8.4 Conventional simulator with fluoroscopy and CBCT

## Final Specifications and Vendor selection

- For a large complex system deciding on the final specifications may be an iterative process involving multiple meetings with the vendor(s).
- Many institutions use external advisory committees/consultants to help them to decide on a short list of vendors with whom to pursue further contract negotiations

## Steps in Development of Contract/Purchase Agreement

- Final contract negotiations may be a multi-step process.
- Once the RFPs have been evaluated the customer may proceed to preliminary contract negotiation with several vendors, possible two or three.
- A "letter of Intent" may be issued to the preferred vendor with a deadline for finalizing a contract.

## Final Contract Negotiations

- The role of the medical physicist at this stage is to be available to address issues related to specifications, installation, acceptance testing, system commissioning, maintenance and downtime and radiation safety issues.

## System Installation

- For a large multi-room system building preparation prior to installation may take 1 to 2 years.
- System installation up to the acceptance of the first treatment room may take ~ 18 months.
- Each additional room requires ~3-4 months before they are accepted.

## Acceptance Testing

- The vendor provided acceptance documents may not be as mature as the acceptance documents that Conventional linac vendors have developed
- Therefore, it may be necessary to negotiate how final acceptance testing of the system is going to be achieved.
- Large multi-room systems are very complex and acceptance testing of the system in a manner similar to that normally anticipated for conventional linac acceptance may not be possible, because it would become unacceptably time consuming.

## Acceptance Testing

- In a large multi-room system installation occurs over an extended period of time, during which several levels of validation and verification (V & V) of system performance are performed.
- At each stage in the installation the vendors are generating V & V documentation. At the later stages high level V & V documentation may be used as part of the acceptance documentation

## Acceptance Testing

- The customer should plan to have medical physics staff available to review high level V & V documents, during the 2 or 3 months before each treatment room will be ready for final acceptance testing.
- The final acceptance testing which should include a series of well defined tests may then be completed in a reasonable time (~ 1 month).
- The details of the overall “acceptance procedures” will probably be negotiated as part of the final contract.

## Commissioning

- Once the first room is accepted. The contract must allow time for the customer to perform commissioning.
- However, the vendor still requires time to complete installation, V & V and acceptance in the other rooms.
- Both the customer and vendor will need beam time and the system will be running on a high duty cycle.
- Once commissioning is completed patient treatments will start creating another demand on beam time.
- The contract should address this issues, since as further rooms are made operational the customer and vendor will be "competing" for beam time.

## System Maintenance

- Proton therapy systems are very complex and it is advisable to have a high level maintenance contract with vendor.
- Advantages of this are that up-time guarantees can be built in to the maintenance contract with penalties for performance below agreed standards. It also gives the vendor the responsibility for maintaining the system at the "acceptance" level.

## Final Contract Negotiations

- The primary negotiator should be an MBA with considerable negotiating experience.
- Institution lawyers will be responsible for drafting the contract.
- It may take many months to negotiate the final contract.