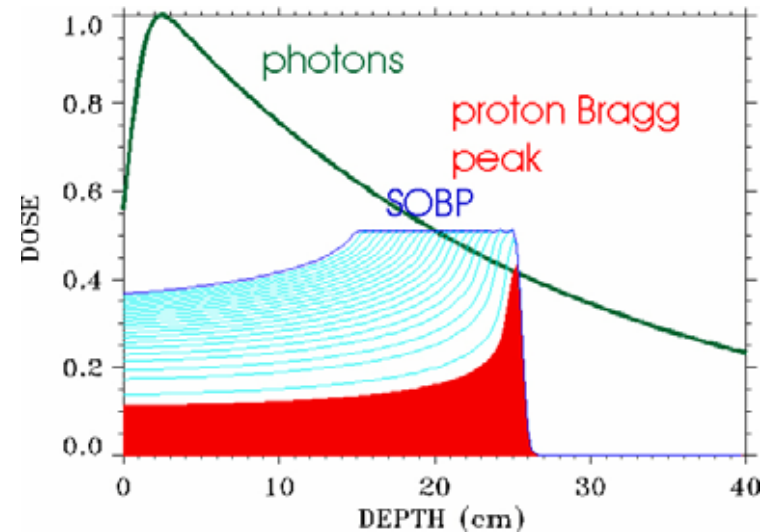


Use of Protons in Clinical Trials

Dec 1, 2006

To: CTEP (regarding a COG protocol)

From: J. Deye and B. Vikram



suggested there be a moratorium on any further approval of the use of proton beams in clinical trials until minimum criteria required in any such multi-institutional trial are formulated

Use of Protons in Clinical Trials

CHARGE TO THE WRITING COMMITTEE

(Drs. Mendenhall, Gillin and Urie)

“draft guidelines for the quality assurance aspects of protons when they are employed in NCI-sponsored clinical trials”

Use of Protons in Clinical Trials

The guidelines should promote comparable treatment regimens as well as criteria which can be reviewed by the QA centers and study chairs.

We envision that these guidelines:

- a) will be concise recommendations (no need for historical reviews)
- b) will deal primarily with the physics, dosimetry and QA of protons (i.e. the material that is usually covered in section 6 of an RTOG protocol)
- c) will be compatible with (or at least not contradictory to) published or soon to be published recommendations; for example from AAPM and ICRU.
- d) will be able to cover multiple treatment sites
- e) will be defensible to CTEP

Use of Protons in Clinical Trials
Draft Recommendations

- Limit the guidelines to passively scattered/modulated modes
(not allow scanned beams until further experience)

Use of Protons in Clinical Trials

QA concerns for Clinical Trials

Calibration

Treatment planning

Treatment delivery

Use of Protons in Clinical Trials
Draft Recommendations

Calibration:

- All sites must use same protocol
- IAEA TRS 398
 - reasonable
 - will be recommended protocol of ICRU
 - ion chamber based on Cobalt-60
- TLD system of RPC be employed annually
(once it is established ?2007?)

Use of Protons in Clinical Trials
Draft Recommendations

“Calibration”:

- All sites must use a standard RBE
 - suggest 1.1

Use of Protons in Clinical Trials
Draft Recommendations

Treatment planning

- CT scan/simulation required
- HU to physical density calibration curve
 - Must be constructed for each site
 - Should be independently reviewed
- Successful irradiation of the RPC lung phantom

Use of Protons in Clinical Trials
Draft Recommendations

Treatment planning

- Protocols should specify dose in terms of minimum dose to a well specified volume
for photons and protons
- PTVs may be different for protons
 - Account for uncertainties

Use of Protons in Clinical Trials
Draft Recommendations

Treatment delivery

- Require ability to acquire diagnostic quality setup portals
- Credentialed for method of monitor unit determination