Proposed Revised NCI Guidelines for Use of Protons in NCI Sponsored Clinical Trials

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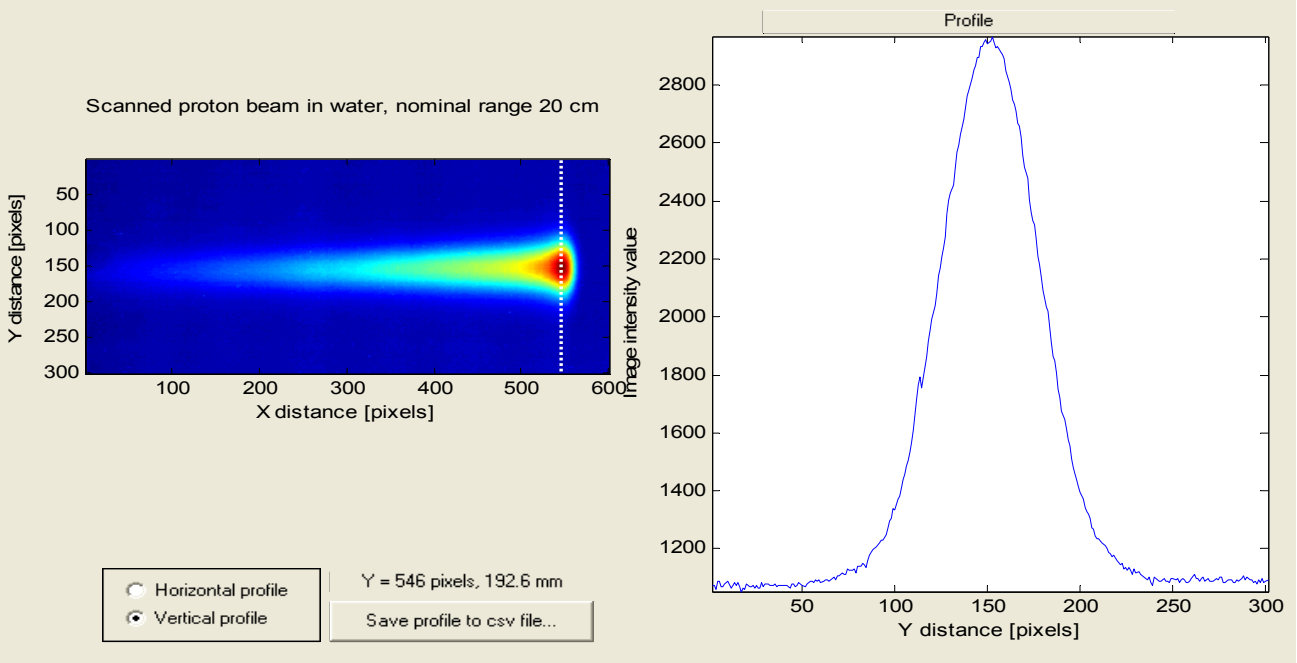
November 2009 Version



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Proposed Guidelines

- 1. Institution must be credentialed, which includes:
  - Successful RPC site visit
  - Ability to transfer plans to the ITC
  - Appropriate documentation of proton dosimetry system from dose to water to dose to patient
  - Other protocol specific or QA Center requirements.

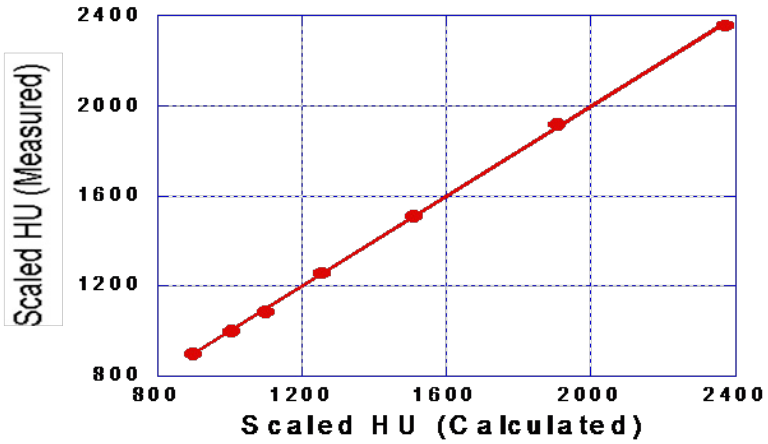
Proposed Guidelines

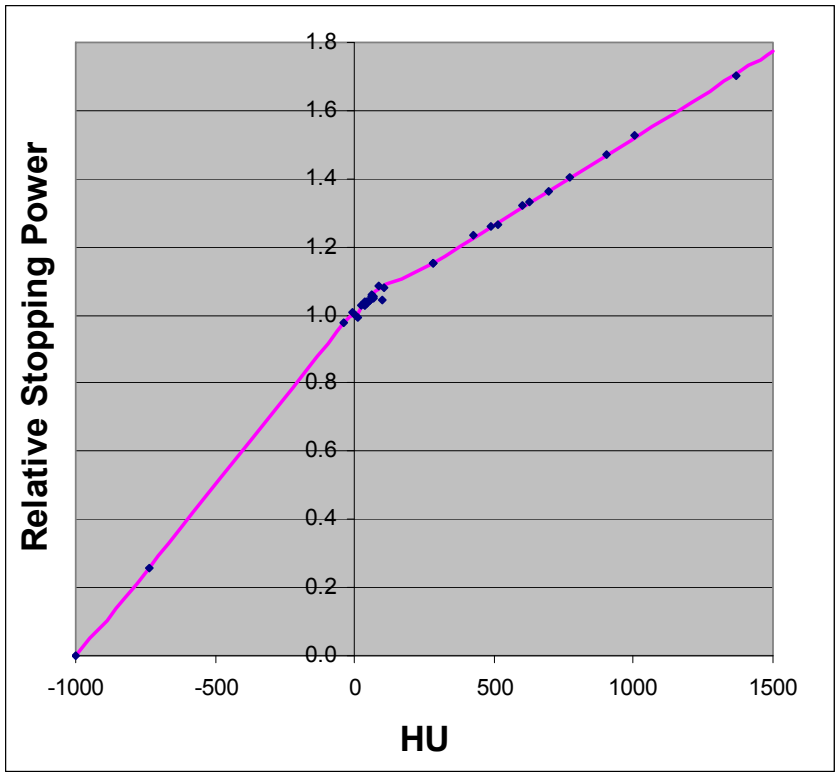
- 2. Both passive and scanned beams may be used, assuming that the specific delivery system (passive or scanned) has been reviewed by the RPC.
- 3. The IAEA TRS 398 protocol is recommended by beam calibration, although ICRU 59 is acceptable. The RPC uses the IAEA protocol during its site visits.

Proposed Guidelines

- 4. All doses shall be expressed as RBE-weighted absorbed dose, D_{RBE}, employing a standard RBE of 1.1 with respect to Co-60. The unit of the RBE-weighted dose is gray (Gy).
- 5. Treatment planning shall be performed on a CT scan obtained with the patient in treatment position. Correlation between the institutional 'CT treatment planning system Hounsfield Units' and 'relative spotting power' must be established and documented at each institution. This will be reviewed during the RPC site visit.

HU, Relative Stopping Power Calibration Curve





Relative electron density

$$HU_{sc} = HU + 1000 = \rho_e (A \tilde{Z}^{3.62} + B \hat{Z}^{1.86} + C)$$

Photoelectric

Coherent

Incoherent

Summary of Typical Penetration Uncertainties

standard energy (or range)	± 0.6 mm
energy (or range) reproducibility	± 1.0 mm
bolus WET	± 0.9 mm
alignment devices*	± 1.0 mm
CT# accuracy (after scaling)	± 2.5%
RLSP of tissues and devices	± 1.6%
energy dependence of RLSP	± 1.0%
CT# to RLSP (soft tissues only)	± 1.5%
bolus position relative to patient	variable
heterogeneity straggling	variable
patient motion	variable

Range Uncert.
2 mm

CT Uncert.
3.5%

Planning
bolus expansion
multiple angles

Moyers PTCOG 2008

Proposed Guidelines

- 6. Doses will be specified using the standard nomenclature (GTV, CTV, PTV). The GTV and CTV shall be identical for protons and photons. Every protocol which permits protons must explicitly address unique to protons in specifying the PTV, such as range uncertainties and lateral scatter. ICRU 78 recommends that the PTV be defined relative to the CTV on the basis of lateral uncertainties alone and that an adjustment be made within the beam-design algorithm to take into account the uncertainties in the beam direction.

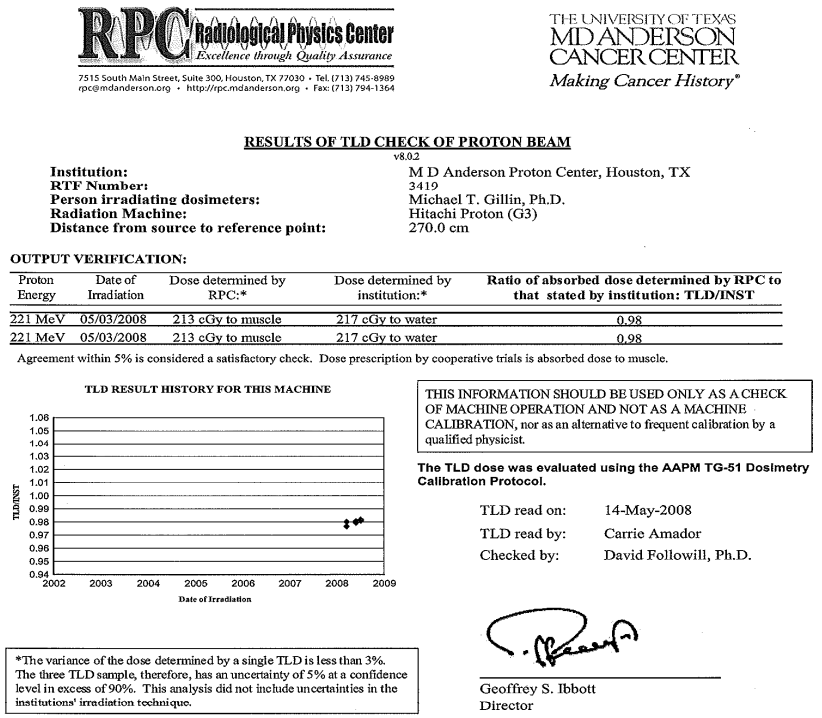
Planning Margins

- Beam specific margins
- Distal margin from CTV = **(3.5% CTV_{dis}) + 3 mm***
- Proximal margin $\geq$ **(3.5% CTV_{prox}) + 3 mm***

* Moyers, IJROBP (2001)

Proposed Guidelines

- 7. In addition to the site visit, the RPC shall conduct annual remote monitoring of the proton calibrations as they relate to the clinical trials in which the facility is participating.



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RESULTS OF TLD CHECK OF PROTON BEAM
v8.0.2

Institution:	M D Anderson Proton Center, Houston, TX
RTF Number:	3419
Person irradiating dosimeters:	Michael T. Gillin, Ph.D.
Radiation Machine:	Hitachi Proton (G3)
Distance from source to reference point:	270.0 cm

OUTPUT VERIFICATION:

Proton Energy	Date of Irradiation	Dose determined by RPC:*	Dose determined by institution:*	**Ratio of absorbed dose determined by RPC to that stated by institution: TLD/INST**
221 MeV	05/03/2008	213 cGy to muscle	217 cGy to water	0.98
221 MeV	05/03/2008	213 cGy to muscle	217 cGy to water	0.98

Agreement within 5% is considered a satisfactory check. Dose prescription by cooperative trials is absorbed dose to muscle.

TLD RESULT HISTORY FOR THIS MACHINE

THIS INFORMATION SHOULD BE USED ONLY AS A CHECK OF MACHINE OPERATION AND NOT AS A MACHINE CALIBRATION, nor as an alternative to frequent calibration by a qualified physicist.

The TLD dose was evaluated using the AAPM TG-51 Dosimetry Calibration Protocol.

TLD read on: 14-May-2008
TLD read by: Carrie Amador
Checked by: David Followill, Ph.D.

Geoffrey S. Ibbott
Director

*The variance of the dose determined by a single TLD is less than 3%. The three TLD sample, therefore, has an uncertainty of 5% at a confidence level in excess of 90%. This analysis did not include uncertainties in the institutions' irradiation technique.

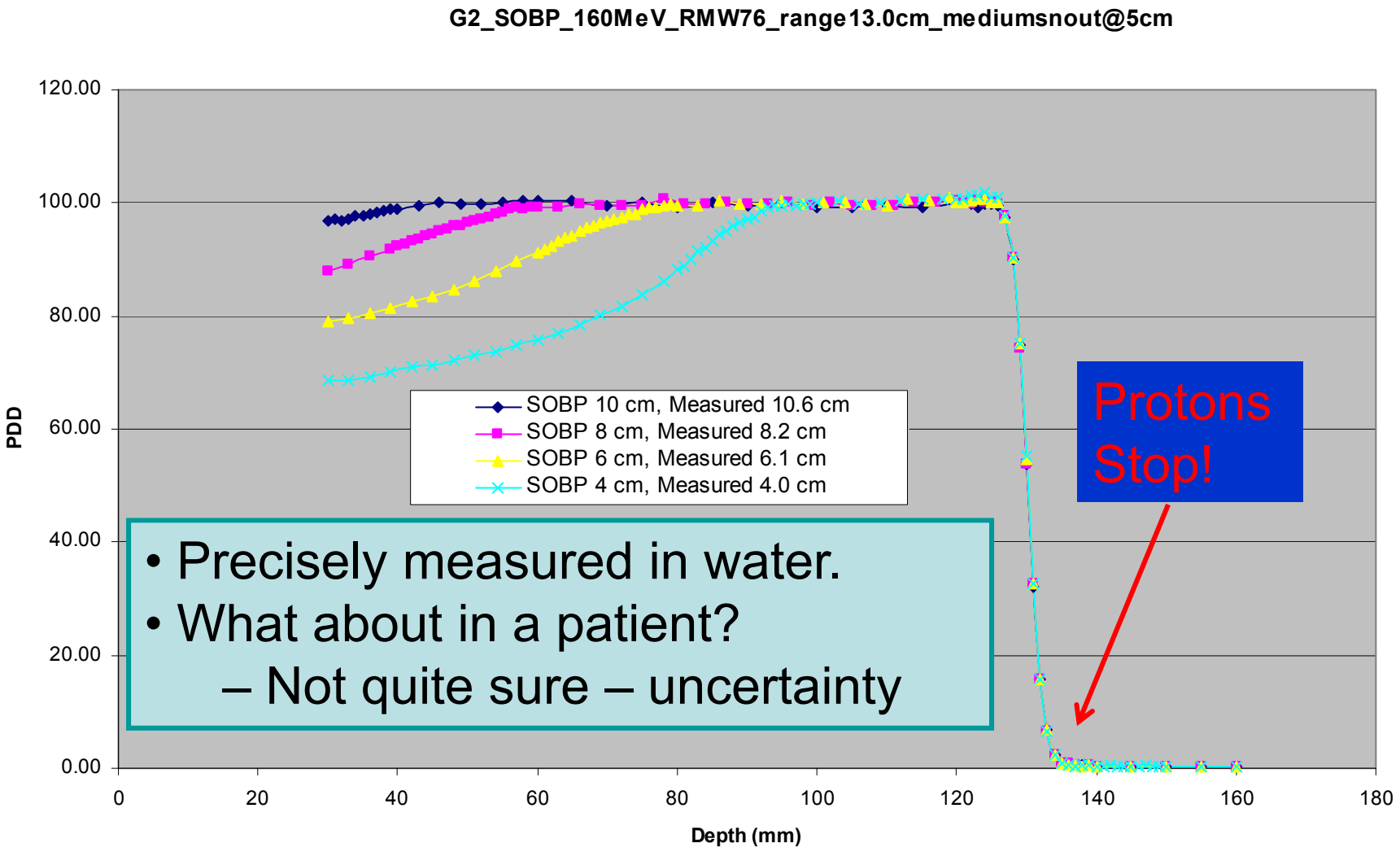
G3 RPC TLD

American Association of Physicists in Medicine
The Radiological Physics Center is a nonprofit, NCI-funded resource to the radiation therapy and medical physics communities. The AAPM provides scientific expertise and technical advice through the Therapy Physics Committee.

Proposed Guidelines

- 8. Every protocol that allows protons must specify a radiation oncologist actively practicing at a proton facility who will be responsible for incorporating into that protocol the appropriate dose terminology and specific constraints related to the PTV and OAR.

Introduction



- Precisely measured in water.
- What about in a patient?
  - Not quite sure – uncertainty