

Radiological Physics Center (RPC) Approval of Proton Centers for NCI-Sponsored Clinical Trials



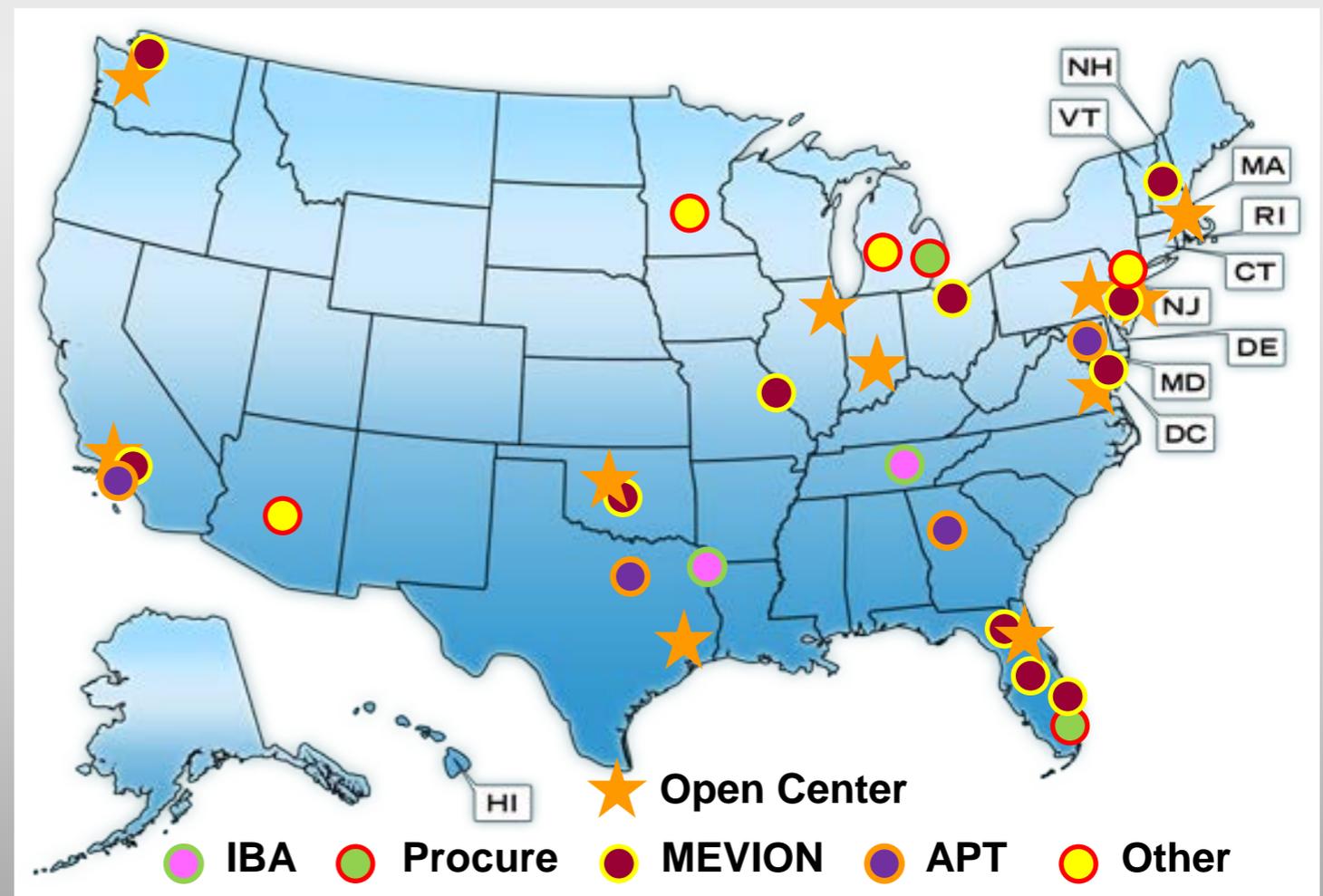
Paige Summers, MS

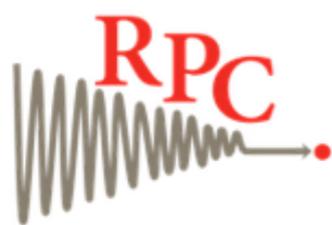
This project is supported by the Federal Share of program income earned by Massachusetts General Hospital on C06 CA059267, Proton Therapy Research and Treatment Center and by grants CA10953 and CA81647 (NCI, DHHS).



Proton Therapy Facilities

- 12 clinically-active proton therapy centers currently
- MANY more centers in development & under construction





Proton Approval

[Approval Process](#)[Proton Facility Questionnaire](#)[Annual Output Calibration](#)[Electronic Data Transfer](#)[Baseline Proton Phantoms](#)[On-site Visit](#)[Pre-Visit Forms](#)

Before an institution can begin the approval process to enroll patients in NCI-funded cooperative group clinical trials, they must be a member of an NCI-funded cooperative group. Currently, both RTOG and COG have protocols with proton radiation therapy. See [RTOG](#) or [COG](#) for membership information.

Prior to an institution being allowed to enroll any patients on a cooperative group protocol with proton radiation therapy, an institution must be approved for the use of protons in clinical trials. This approval process consists of:

1. Completion of the [proton facility questionnaire](#).
2. Annual monitoring of the proton beam calibrations by the RPC.
3. Ability to [electronically transfer treatment plans](#).
4. Successful irradiation of the RPC's baseline proton phantoms.
5. Successful completion of an on-site dosimetry review visit and visit report to occur only after the center has been routinely treating patients for a minimum of 6 months with no fewer than 3 disease sites.

The RPC will coordinate the completion of the approval processes in conjunction with the other quality assurance offices.

RPC Proton Site Visits

- NCI/RPC recommend institutions only visited after center has been routinely treating patients for minimum of 6 months with no fewer than 3 disease sites
- Different delivery modalities have separate audit requirements – must *each* be reviewed (e.g. passive scatter vs. spot scanning)
- Proton therapy site visit fee \$12,000
- Prioritization dependent on institution's initiative, membership in cooperative groups, readiness

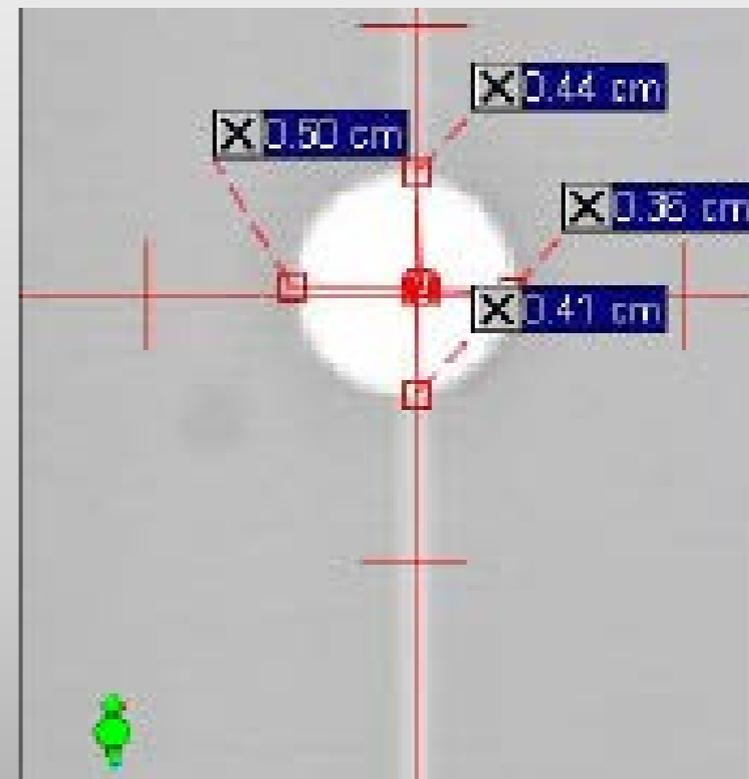
Established Criteria

- Output

- Reference Field – water tank TRS 398 measurement: $\pm 3\%$
- Patient Fields – ion chamber array CAX dose: $\pm 5\%$

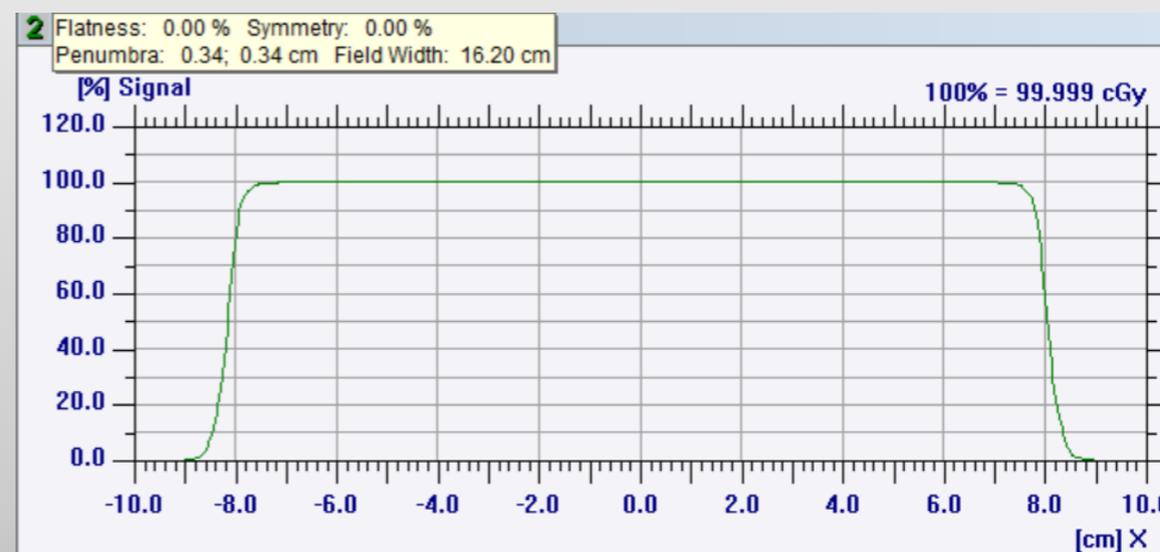
- IGRT Test

- OBI and radiation isocenter coincidence - film: $\pm 2 \text{ mm}$



New Criteria

- Reference Field Lateral Profiles – ion chamber array CAX
 - Flatness: $\pm 2\%$
 - Symmetry: $< 3\%$
 - Lateral Penumbra: $\pm 3\text{ mm}$



New Criteria

- Range - MLIC measurement: ± 3 mm

	Range Comparison: $\text{Range}_{\text{Measured}} - \text{Range}_{\text{Institution}}$							
	Anatomy Simulated							
	Reference	Prostate	Lung	Brain	Spine	Pituitary	H&N	OVERALL
Max [mm]	0.5	0.8	0.6	1.3	0.5	0.0	-0.1	1.3
Min [mm]	-1.9	-2.6	-1.5	-2.6	-1.0	0.0	-0.1	-2.6
Mean [mm]	0.6	1.5	0.5	1.0	0.3	0.0	0.0	0.6
Std Dev [mm]	0.8	1.2	0.8	1.5	0.7	N/A	N/A	1.0

New Criteria

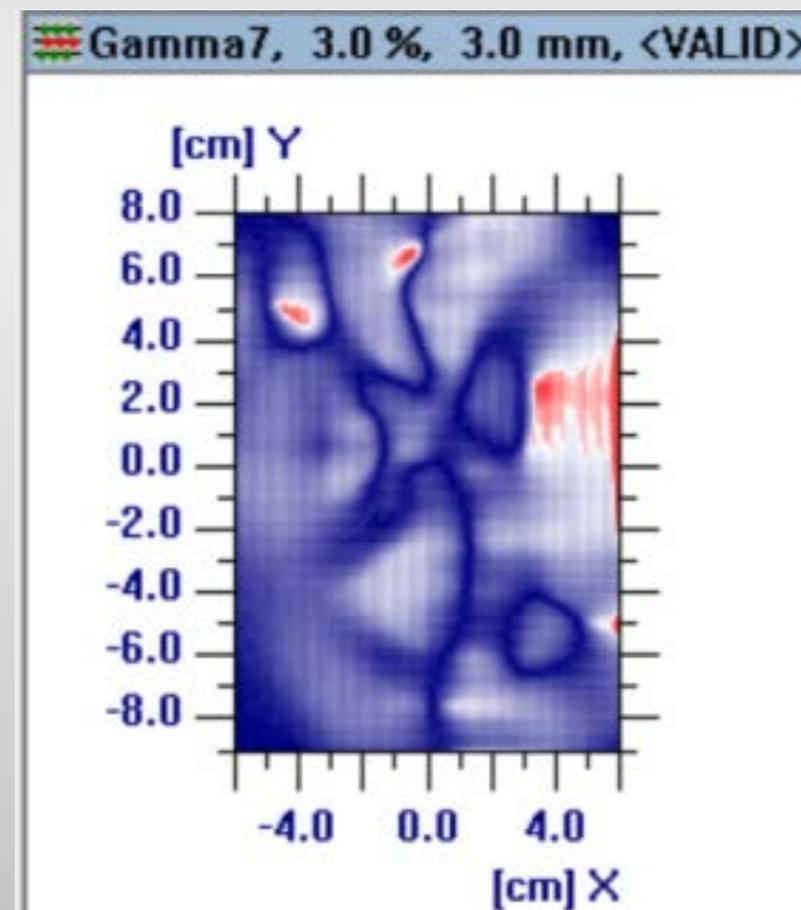
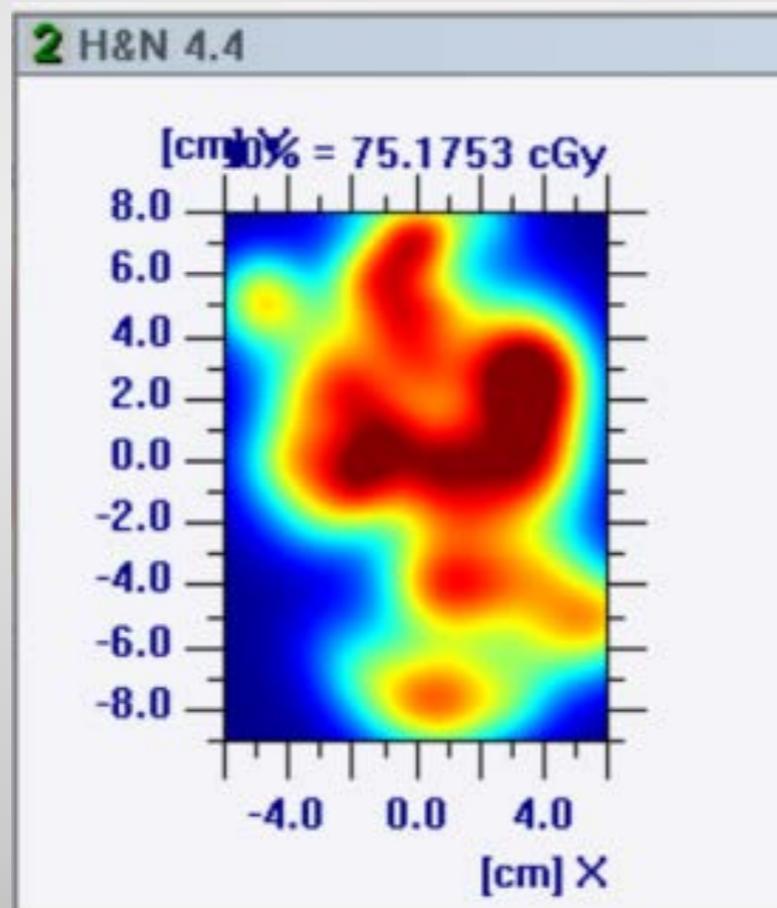
- SOBP Width - MLIC measurement: ± 5 mm

	WOBP Width Comparison: $\text{SOBP}_{\text{Measured}} - \text{SOBP}_{\text{Institution}}$							
	Anatomy Simulated							
	Reference	Prostate	Lung	Brain	Spine	Pituitary	H&N	OVERALL
Max [mm]	4.6	3.1	3.9	3.0	0.5	2.3	3.2	4.6
Min [mm]	-3.3	-2.5	-3.0	-2.8	-3.0	2.3	3.2	-3.3
Mean [mm]	2.4	2.5	1.1	1.4	0.6	0.8	3.2	1.7
Std Dev [mm]	3.3	2.2	2.5	2.4	1.6	N/A	N/A	2.4

New Criteria

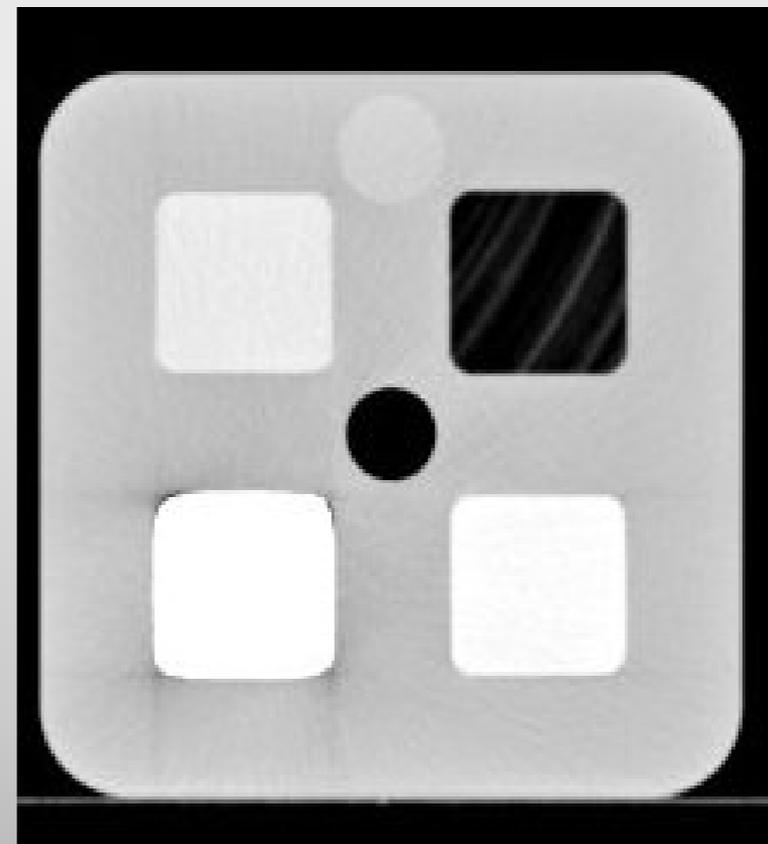
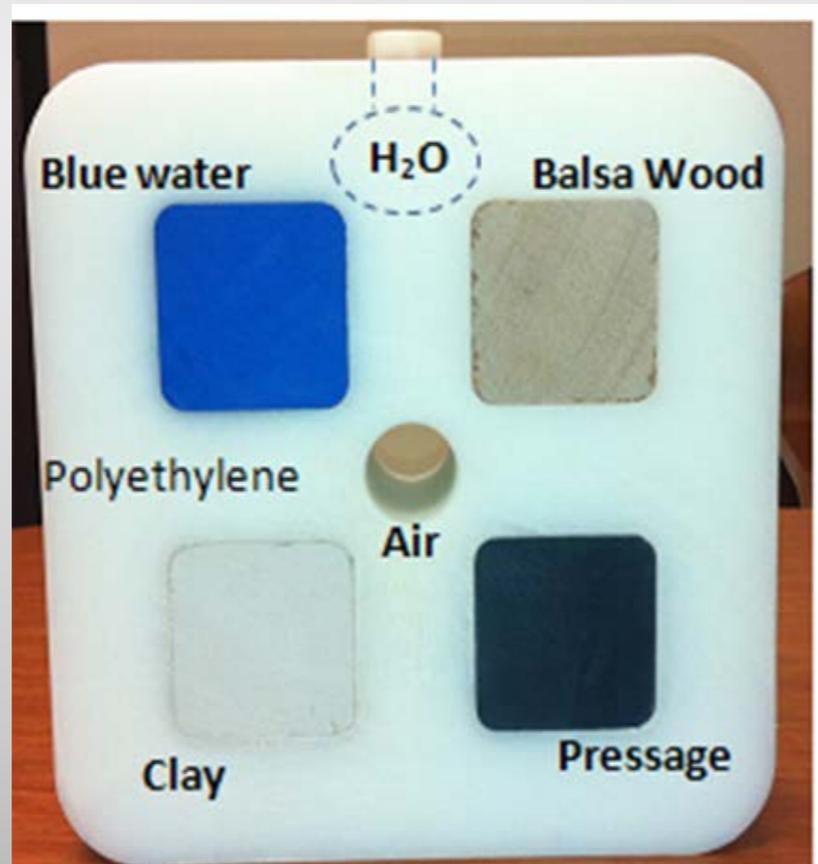
- Field Dosimetry

- Reference & Patient Fields – ion chamber array gamma 3%/3mm: 90% of pixels passing



Criteria still to come...

- CT-RSP phantom – designed to test institutions HU-RSP conversion curves
- Will assess criteria as phantom is used at more institutions



Questions?

