

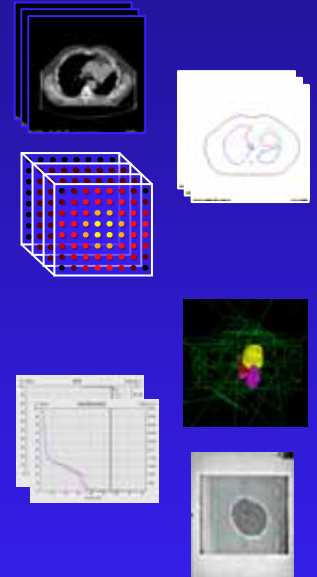
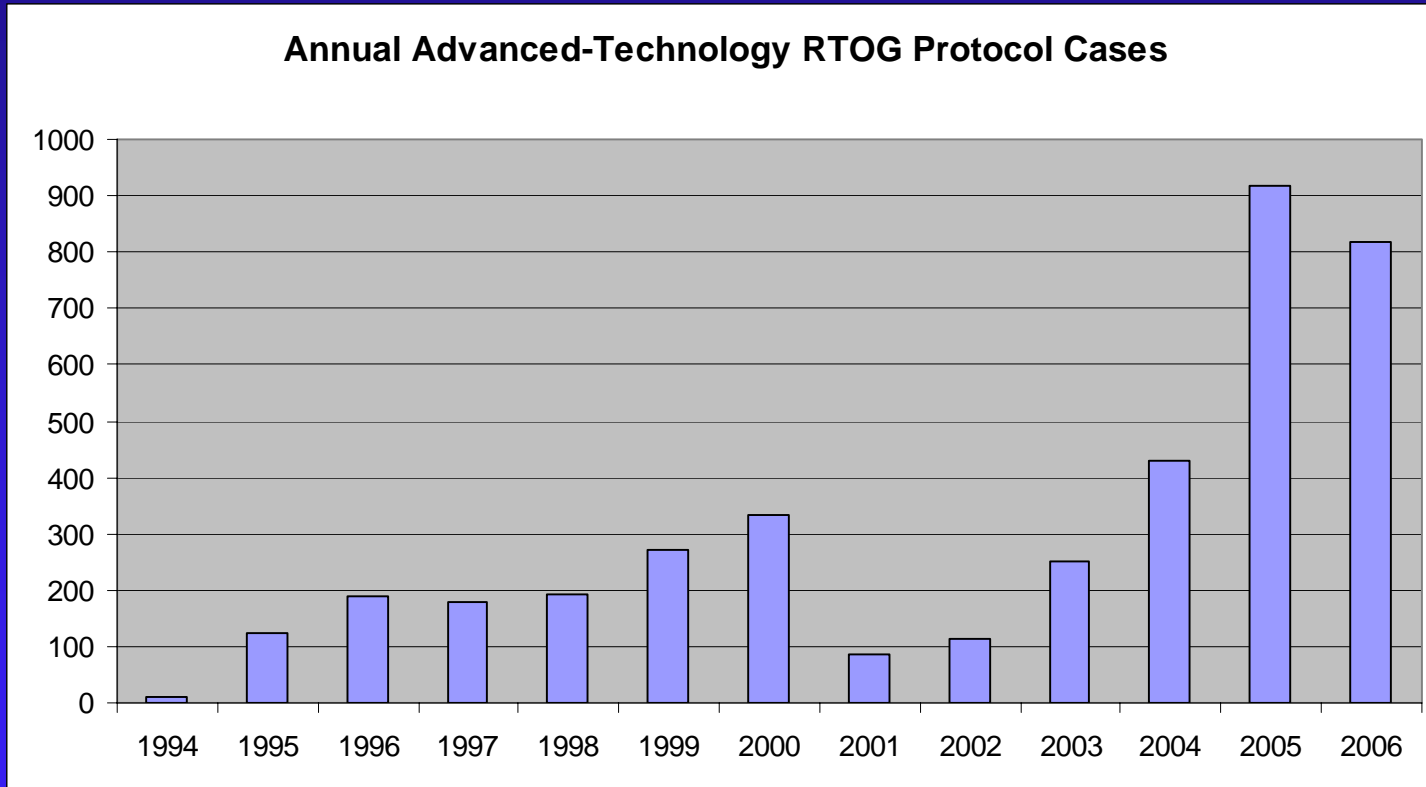
Principal Investigator's Report Advanced Technology QA Consortium

**RTOG Meeting – Tampa, Florida
February 1, 2007**

**James A. Purdy, Ph.D.
Department of Radiation Oncology
UC Davis Medical Center
Sacramento, CA, USA**

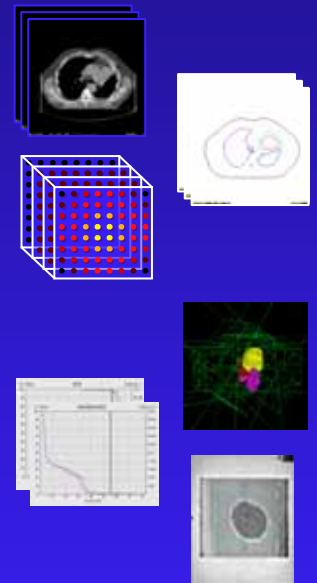
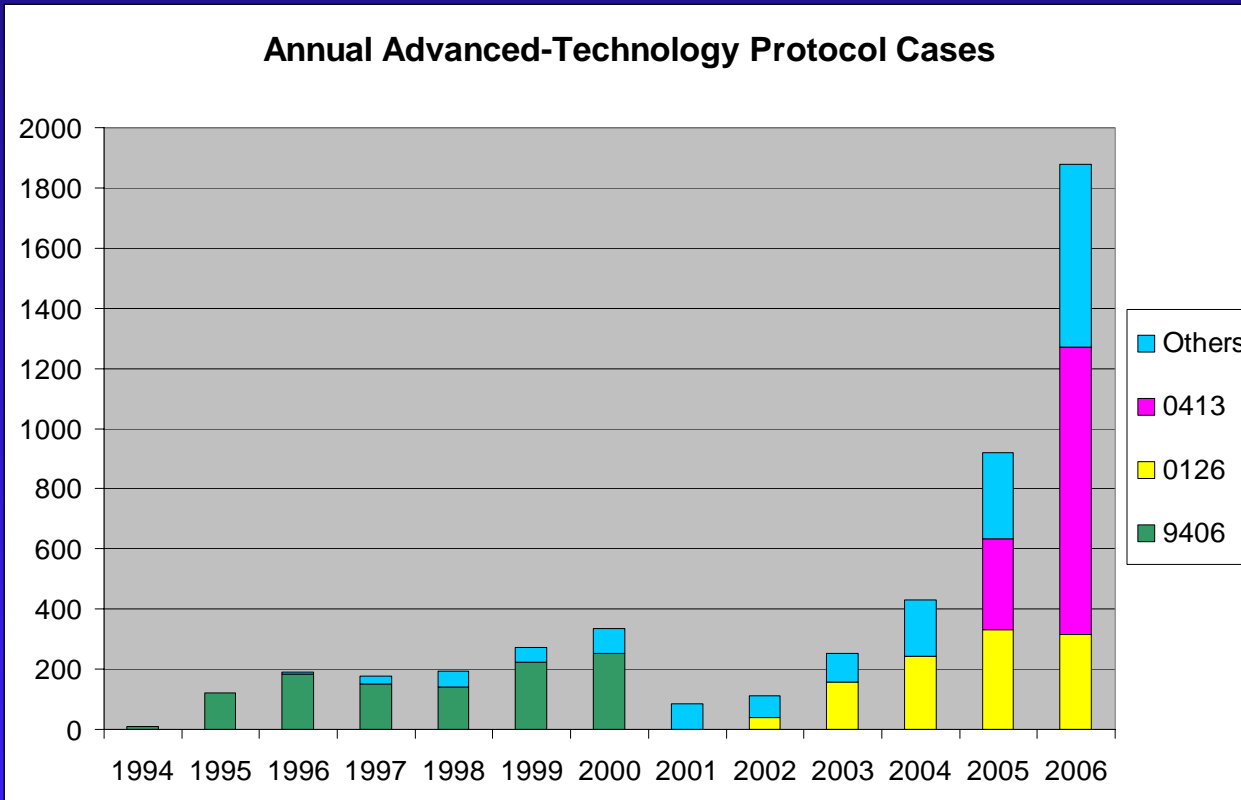
Supported by NIH U24 grant CA81647,
“Advanced Technology QA Center”

- **June 22 2006 ATC Mtg: 3913 Complete, Protocol-Case, Volumetric Digital Data Sets Submitted Over 12+ Year Period using ATC Method 1**



- **8 commercial TPS vendors (15 TPSs) have implemented ATC compliant export capability.**
- **418 institutions able to submit data**

- **January 2007 ATC Mtg: 4974 Complete, Protocol-Case, Volumetric Digital Data Sets Submitted Over 13 Year Period using ATC Method 1**



- **8 commercial TPS vendors (15 TPSs) have implemented ATC compliant export capability.**
- **486 institutions able to submit data**

ATC Compliant Treatment Planning Systems (as of January, 2007)

Vendor	Treatment Planning Systems		Exchange Format	Treatment Modality				
	System	Version *		3DCRT	IMRT	Seed Brachy	HDR Brachy	Protons
CMS	Focus/XtO	3.1	R	✓	✓	✓		✓
	XtO	4.3.1**	D	✓	✓			
Elekta	RenderPlan 3D		R	✓				
	PrecisePlan	2.01	D	✓	✓			
Nomos	Corvus		R		++			
Nucletron	Helax TMS		R	✓	✓			
	TheraPlan Plus		R	✓				
	PLATO RTS	2.62	D	✓				
	PLATO BPS	14.2.6	D				✓	
Philips	Pinnacle ³		R	✓	✓			
	AcqPlan	4.9	R	✓				
Rosser Medical	Strata Suite CTPlan	4.0	R			✓		
RTek	PIPER	2.1.2	R			✓		
Varian	BrachyVision	6.5 (Build 1.1.07)	D				✓	
	Eclipse	7.1	D	✓	✓			✓
	VariSeed	7.1	D			✓		

Exchange formats for submission of ATC Protocol Data: **D** = DICOM RT Objects **R** = RTOG Data Exchange Format

10 Closed RTOG Digital Data Protocols (Jan., 2007)

Protocol	Description
9406	Ph I/II 3DCRT Prostate Dose Escalation
9311	Ph I/II 3DCRT Lung Dose Escalation
9803	Ph I/II 3DCRT GBM Dose Escalation
0022	Ph I/II 3DCRT/IMRT Oropharynx
0225	Ph I/II 3DCRT/IMRT Nasopharynx
0234	Phase II Randomized Trial of Surgery Followed by Chemoradiotherapy Plus C225 (Cetuximab) for Advanced Squamous Cell Carcinoma of H&N
0236	Ph II SBRT Lung
0319	Ph I/II 3DCRT Partial Breast
0321	Ph I/II HDR/Ext Beam Prostate
0421	Phase III Trial for Previously Irradiated Head and Neck Cancer: Re-irradiation with or without Chemo

10 RTOG Protocols Actively Supported by ATC (Jan., 2007)

Protocol	Description
0117	Ph I/II 3DCRT/chemo Lung
0126	Ph III 3DCRT/IMRT Prostate
0232	Ph III Ext Beam/TIPPB Prostate
0413	Ph III Partial Breast Irradiation
0415	Phase III Rand Conventional Fx 3DCRT/IMRT vs Hypo Fx 3DCRT/IMRT in Prostate Ca
0418	Phase II IMRT + / - chemo for post-op endometrial or cervical Ca
0438	Phase I Unresect. Primary Bil Hepatobil. Ca & Liver Mets Extracranial Stereotactic RT
0515	Phase II NSCLC Volume definition+/- PET
0521	Phase III localized High Risk Prostate Cancer: Androgen Suppression with Radiation vs. Radiation with Chemotherapy and Prednisone
0522	Phase III Trial Comparing Radiation and Cisplatin with/without Cetuximab for Advanced Head and Neck Cancer

1 NSABP/RTOG ATC Supported Protocol (January, 2007)

Protocol	Description	Accrual Goals	Institutions Credentialed	Cases Accrued
NSABP B39 RTOG 0413	Phase III Partial Breast Irradiation	4300	400 (328CRT/241M/ 37MC)	2560 (1019CRT/249M/ 78MC)

QARC ATC Supported Open Protocols (Jan., 2007)

- *ATC Method 1* (ITC's software for submission and review of 3-dimensional images/RT objects) has been implemented at QARC.
- Volumetric DICOM and RTOG format data can be imported into the ATC Method 1 server at QARC using either CD media or the FTP server at QARC.
- Data imported into the Method 1 server can be reviewed using the Remote Review Tool on any QARC desktop PC.
- The Remote Review Tool can be invoked directly from the QARC database user interface.
- Protocols supported by QARC in which volumetric digital data submission is encouraged are: (1) COG ACNS0126 Phase II Glioma; (2) COG ACNS0331 Phase III Medulloblastoma; (3) COG ACNS0121 Phase II Ependymoma; and (4) CALGB 80101 Phase III Gastric/Gastroesophageal
- 50+ institutions submitting data in this fashion.

ATC Supports NCIC

- The National Cancer Institute of Canada (NCIC) has successfully implemented *ATC Method 3* (RCET's NetSys for submission and review of 2-dimensional images and text documents) for support of NCIC MA20 a phase III study of regional radiation therapy in early breast cancer.
- NCIC has agreed to work with RCET and test/implement *ATC Method 2* (RCET's NetSys/WebSys software for submission and review of 3-dimensional images/RT objects).
- ATC (RPC, ITC) has worked with NCIC in developing RT forms for Prostate START protocol.

ATC Supports JCOG 0403: Ph II Study of SBRT In Patients with T1N0M0 Non-Small Cell Lung Cancer)

- Institutions participating in protocol JCOG 0403 submit digital data representing CT images, structure sets, treatment plans, 3D dose distributions, and DVHs to Dr. Satoshi Ishikura, Director of the Radiotherapy Support Center, Tokyo, JAPAN, who then forwards these data to ITC in St. Louis for processing.
- Data are reviewed by Dr. Ishikura or his delegate using the ITC Remote Review Tool.
- Currently, 14 institutions are eligible to enroll patients and capable of digital data submission on JCOG 0403; 106 patients are registered to study.



ATC Working with NABTT

- NABTT (Dr. John Fiveash, M.D., Department of Radiation Oncology, University of Alabama Birmingham)
- QA plan agreed upon. Latest is being posted to the NABTT and ATC websites.
- New RT section draft for IMRT to be sent to ATC for review. (has been approved by RadOnc committee in NABTT).
- Plans to add this section to the next available up front GBM study after ATC/CTEP review.

NEW APPROACHES TO BRAIN TUMOR THERAPY

**The New Approaches to Brain Tumor Therapy
CNS Consortium**

Group Leaders: Stuart Grossman, Henry Brem

Member Institutions

- Cleveland Clinic
- Emory University
- Henry Ford Hospital
- Johns Hopkins University
- Massachusetts General Hospital
- Moffitt Cancer Center
- NCI Neuro-Oncology Program
- University of Alabama at Birmingham
- University of Pennsylvania
- Wake Forest University

NABTT Central Operations Office PI: Stuart Grossman, Johns Hopkins University
NABTT Biostatistical Office PI: Steven Plantadosi, Johns Hopkins University
NABTT Pharmacology Center PI: Jeff Supko, Massachusetts General Hospital

ATC Working with EORTC

- ATC is working with the EORTC to provide data integrity QA for the upcoming EORTC Protocol 22042 “Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma: a Phase-II and registration study”.
- Testing of data submission (using SFTP) and review (using RRT) are currently underway.

ATC Supports CDRP

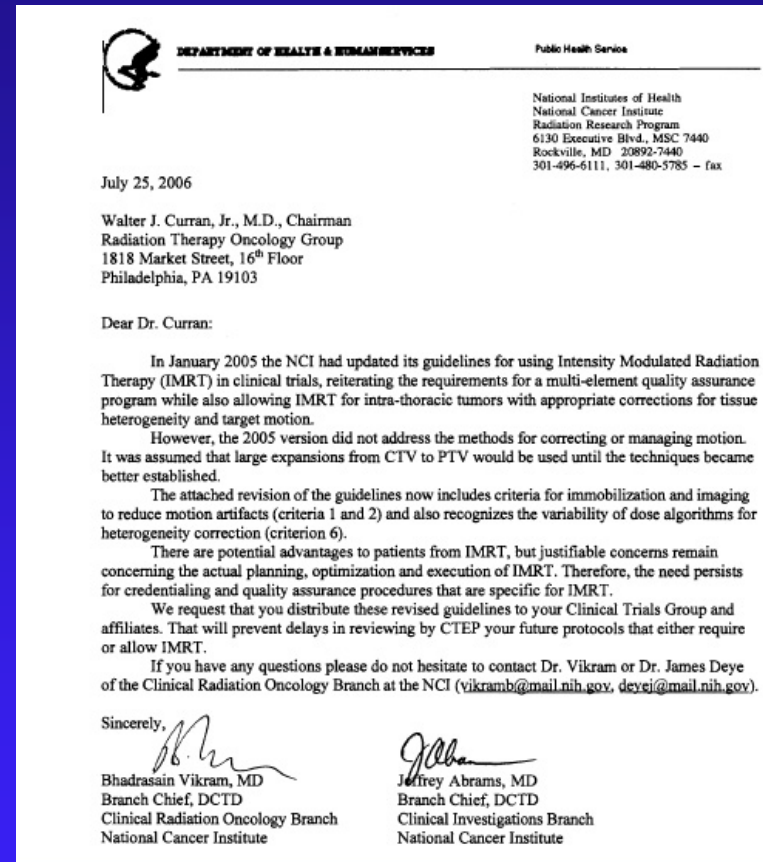
- High priority given to working with CDRP sites regarding credentialing for ATC supported protocols.
- Status of all CDRP sites is reviewed at each monthly ATC teleconference.

ATC is working with caBIG/NCIA

- **ATC is one of the funded participants in the caBIG In Vivo Imaging Workspace.**
 - **ATC members (ITC, RTOG, QARC) and ACRIN are actively participating in the Testbed Special Interest Group (SIG).**
- **ATC members participated in the IVI Workspace face to face meeting held in Rockville, MD, July 20-21, 2006.**
- **ATC members participated in the NIST Workshop on Imaging as a Biomarker: Standards for Change Measurements in Therapy held in Gaithersburg, Maryland on September 14-15, 2006.**
- **ATC members participated in the CIP Workshop on Imaging Informatics in Cooperative Group Clinical Trials held in Bethesda, MD on September 25-26, 2006.**
- **ATC members participated in the NCI Workshop on Advanced Technologies held in Bethesda, MD on September 25-26, 2006.**

NCI IMRT Protocol Requirements Updated

- In Jan. 2005 NCI had updated its guidelines for using IMRT in clinical trials, reiterating requirements for a multi-element QA program while also allowing IMRT for intra-thoracic tumors with appropriate corrections for tissue heterogeneity and target motion.
- However, 2005 version did not address methods for correcting/managing motion as it was assumed that large expansions from CTV to PTV would be used until the techniques became better established.
- In July 2006 NCI updated its 2005 IMRT guidelines to include criteria for immobilization and imaging to reduce motion artifacts and also recognizes the variability of dose algorithms for heterogeneity correction.



ATC is Supporting Industry Clinical Trial

- **ITC support of the AstraZeneca protocol has begun.**
 - **Two of three institutions credentialed**
 - **Case studies have been submitted**

RTOG-ATC Posters/Presentations at 2006 AAPM Annual Meeting

- SU-FF-T-167: Digital Data Integrity QA for Multi-Institutional Clinical Trials, W. Straube*, W. Bosch, J. Matthews, R. Haynes, J. Purdy
- SU-FF-T-169: Dose Calculation Accuracy in the Presence of High-Z Materials using Megavoltage CT for Treatment Planning, R. Hecox*, J. Gibbons, D. Followill, G. Ibbott
- SU-FF-T-255: Heterogeneity dose calculation accuracy in IMRT using an anthropomorphic thorax phantom, S. Davidson*, K. Prado, G. Ibbott, D. Followill
- SU-FF-T-267: Implementation of ATC Method 1 for Clinical Trials Data Review at the Quality Assurance Review Center, W. Bosch*, J. Matthews, K. Ulin, M. Urie, J. Yorty, W. Straube, T. FitzGerald, J. Purdy
- SU-FF-T-308: ITC Assists Developers of ATC Compliant DICOM Export for Clinical Trials, J. Matthews*, W. Bosch, W. Straube, J. Purdy
- SU-FF-T-406: Testing of ATC Method 2 for Supporting QA of Cooperative Group Advanced Technology Clinical Trials Requiring Digital Data Submission, W. Bosch*, S. O'Leary, J. Matthews, V. Frouhar, J. Palta, G. Field, L. Pho, J. Purdy
- SU-FF-T-410: The Credentialing Process for the NSABP B-39/RTOG 0413 Partial Breast Irradiation Trial, J. Lowenstein*, C. Davis, J. Roll, I. Harris, F. Hall, D. Followill, G. Ibbott
- TU-E-224A-1: Evaluation of heterogeneity corrections algorithms through the irradiation of a lung phantom, P. Alvarez*, A. Molineu, N. Hernandez, D. Followill, G. Ibbott
- TU-FF-A1-1: Characterization of EBT versus MD55 GafchromicB films for relative dosimetry measurements, P. Alvarez*, N. Hernandez, D. Followill, R.
- TH-C-230A-9: Implementation of MINERVA/PEREGRINE as an ATC Review Tool, J. Purdy*, J. Lehmann, D. Wessol, J. Cogliati, M. Milvich, C. Frederickson, D. Nigg, C. Wemple
- TH-D-224C-2: The State of Radiotherapy Physics Through The Eyes of a Quality Auditor, D. Followill*, A. Molineu, P. Alvarez, G. Ibbott

RTOG-ATC Posters/Presentations at 2006 ASTRO Annual Meeting

- A Review of the Activities of the ITC in Support of RTOG Advanced Technology Clinical Trials. J.A. Purdy, W.R. Bosch, W.L. Straube, J.W. Matthews, R.J. Haynes, J.M. Michalski, E.A. Martin, K. Winter, W.J. Curran, Jr., and J.D. Cox.
- Report of QA Measurements that were Performed Prior to Irradiations of a Head and Neck IMRT Anthropomorphic Phantom. A. Molineu, P. Alvarez, N. Hernandez, D.S. Followill, G.S. Ibbott.
- Analysis of the irradiation of an anthropomorphic lung phantom including heterogeneities. P. Alvarez, A. Molineu, N. Hernandez, D. Followill, G. Ibbott.
- The Value of Credentialing. J. Lowenstein, J. Roll, D.S. Followill, D., and G.S. Ibbott.
- Phase II Multi-Institutional Study of IMRT for Oropharyngeal Cancer (RTOG 00-22): Early Results. A. Eisbruch, J. Harris, C. Chao, A. Garden, W. Straube, C. Schultz, G. Sanguineti, C. Jones, W. Bosch, W. and K.K. Ang.

ATC Workshop (Special Interest Session) held at 2006 AAMD Annual Meeting

- Held as breakout session from main program
- First session involved Eclipse (8:30 - 9:30); second session involved Pinnacle (10:00-11:00); third session involved Rahd and Nucletron (11:00-12:30)
- Bill Straube presented an overview of ATC and digital data submission to the groups prior to each session and then vendors demonstrated TPS digital data submission UI's.
- All Vendors brought equipment to demonstrate their submission.
- All vendors plan on putting together information for the ATC website.
- ATC should plan to do another workshop at the next AAMD Annual meeting to be held in New Orleans.

ATC WEB SITE Updated (<http://atc.wustl.edu>)



Challenges/Opportunities: ATC Supported Clinical Trials

- Developing a more formal mechanism as to how it is decided as to which clinical trials are to be supported by ATC funding.
- ATC compliant stereotactic radiosurgery or radiotherapy RTP systems and efficient credentialing/QA process
- PET (quantitative) data import and image fusion QA
- 4-D CT (several 100 MB)
- Image-Guided RT (EPID, MV and kVp Cone beam CT, Helical Tomotherapy megavoltage CT)
- Adaptive Radiation Therapy
- Increased use of ATC Method 1 at QARC
- Successful implementation of ATC Method 2 at NCIC
- Move ATC software development effort toward integration with industry informatics efforts and caBIG compliant software

Agenda

- 8:00 AM: Project Officer Report (Deye)
- 8:15 AM: P.I.'s Report (Purdy)
- 8:35 AM: NCI Workshop on *AT in Rad. Oncology* Summary (Vikram).
- 8:35 AM: Update on ATC compliant TPS and IHE Effort (Bosch)
- 8:45 AM: ITC Data Integrity QA Database/Review Issues (Straube/Haynes)
- 9:00 AM: RTOG Developing Protocols needing ATC Support (Martin/Galvin)
- 9:30 AM: RTOG SBRT Localization Credentialing Test (Galvin)
- 9:45 AM: RTOG 0522 Status (Martin/Bosch/Young)
- 9:55 AM: RTOG 0515 Status (Martin/Bosch)
- 10:05 AM: NSABP B39/RTOG 0413 support by ATC (Straube/Ibbott/Martin)
- 10:15 AM: Break
- 10:30 AM: RPC Phantom/IMRT benchmark credentialing (Ibbott)
- 10:45 AM: Dose Cal. Alg./Heterogeneity Corr. issues (Ibbott/Alvarez)
- 11:15 AM: QARC/RPC 3DCRT Benchmark (Urie)
- 11:30 AM: QARC use of ATC Method 1 (Ulin)
- 11:45 AM: Image DB for RT Clin. Trials/QARC caBIG IVI efforts (FitzGerald)

Agenda

- 1:15 PM: NCIC report on implementing ATC Method 2 (Field/Palta)
- 1:30 PM: RCET report on other related efforts (Palta/Frouhar)
- 1:45 PM: Report on CERR developments (Deasy)
- 2:15 PM: Industry informatics efforts within ATC (CMS, TeraMedica, IMPAC Eclipse)
- 2:45 PM: Update on EORTC ATC Efforts (Bosch/Purdy)
- 2:45 PM: Update on GENEPI Workshop (Bosch/Purdy)
- 2:55 PM: Update on NABTT ATC Support (Purdy)
- 3:05 PM: Status of JCOG 0403 Protocol (Ishikura)
- 3:15 PM: ATC support-NCI guidelines for protons in protocols (Deye/Urie)
- 3:30 PM: RTOG 0626 status (DeLaney)
- 3:45 PM: Adaptive Radiation Therapy Clinical Trials Requirements (Michalski)
- 4:00 PM: New Credentialing Proposal: (Straube)
- 4:15 PM: Transfer of RTOG case compliance QA database (Straube/Martin)
- 4:30 PM: Review of ATC Priority List and Open Discussion (Purdy and all participants)
- 5:00 PM: Adjourn

Current Credentialing Requirements for RTOG Protocols

Protocols	Facility Questionnaire	ITC Digital Data Subm. Capability	Knowledge Assessment	Protocol Specific Dry Run (down-loaded data)	Protocol Specific Dry Run (prev. treated case)	First Case Review (Rapid)	First Case Review (Timely)	Patient Immob. Test	Planning/Delivery Test (see table below)
QARC	X								A or B or C
RTOG 0022	X	X			X				C
RTOG 0117	X	X			X				n/a
RTOG 0126 (3D)	X	X			X				n/a
RTOG 0126 (IMRT)	X	X			X				B or C
RTOG 0225	X	X			X				C
RTOG 0234	X	X							A or B or C
RTOG 0236	X	X				X		X	D
NSABP B-39/RTOG 0413	X	X	X	X		X			n/a
RTOG 0418	X	X				X			B
RTOG 0421 (IMRT)	X	X					X		C
RTOG 0438	X	X			X	X		X	D
RTOG 0521	X	X							A or B or C
RTOG 0522 (IMRT)	X	X					X		C

Level	QARC IMRT Benchmark	RPC Phantom		
		Simple (Pelvis or Brain)	Complex (Head/Neck)	Protocol Specific
A	X			
B		X		
C			X	
D				X