RTOG
Radiation Therapy Oncology Group

RTOG Report to ATC

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RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of October 21, 2009)

- 3D-CRT and IMRT Protocols
  - Active Protocols (20)
    - RTOG 0413/NSABP B39: Phase III Study of Whole Breast RT versus Partial Breast Irradiation
      - 613 institutions credentialed (462 3DCRT, 326 Mammosite, 56 Multi-Cath); 3569 patients registered to study (1366 3DCRT, 335 Mammosite, 100 Multi-Cath, 1768 WBI)
    - RTOG 0415: Phase III study of Hypofractionated 3D-CRT/IMRT versus Conventionally Fractioned 3D-CRT/IMRT in Patients Treated for Favorable-Risk Prostate Cancer
      - 419 institutions credentialed; 1074 patients registered to study; Target Accrual – 1067
    - RTOG 0436: Phase III Esophagus, Cetux/Cis/RT vs Cis/Taxo/RT; 3D-CRT
      - 257 institutions credentialed; 90 patients registered to study; Target Accrual – 420
    - RTOG 0524: Phase I/ II Bladder

      - 106 institutions credentialed; 39 patients registered to study;

        Target Accrual-88

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of October 21, 2009)

- 3D-CRT and IMRT Protocols (20) (cont.)
  - RTOG 0534: Phase III RT Whole Pelvis vs Prostate Bed in High Risk Patients; 3D-CRT/IMRT
    - 293 institutions credentialed; 178 patients registered to study; Target Accrual – 1764
  - RTOG 0539: Phase II Feasibility study of IMRT Intermediate & high risk Meningiomas, & observation for Low risk
    - 12 institutions credentialed; 12 patients registered to study; Target Accrual – 165
  - RTOG 0617: Phase III High Dose 3DCRT in (Taxo/Cis) NSCLC
    - 215 institutions credentialed; 163 patients registered to study; Target Accrual – 512
  - RTOG 0619: Phase II IMRT, Chemo, ZD6474 for High Risk Post Op H&N
    - 96 institution credentialed; 11 patients registered to study; Target Accrual – 170

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of October 21, 2009)

- 3D-CRT and IMRT Protocols (20) (cont.)
  - RTOG 0621: Phase II Prostate RT/AS & Docetaxel; IMRT
    - -190 institutions credentialed; 42 patients registered to study; Target Accrual – 76
  - RTOG 0622: Phase II Prostate Samarium 153; IMRT/3DCRT
    - 177 institutions credentialed; 7 patients registered to study; Target Accrual – 76
  - RTOG 0630: Phase II IGRT Large Size Soft Tissue Sarcoma; 3D-CRT/IMRT
    - 23 institutions credentialed; 42 patients registered to study; Target Accrual - 102
  - RTOG 0631: Phase II/III Stereotactic Radiosurg for Spine Mets
    - 1 institution credentialed; 13 in the process; 0 patients registered to study; Target Accrual –Phs II 43 Phs III 240

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of October 21, 2009)

- 3D-DRT and IMRT Protocols (20) (cont.)
  - RTOG 0712: Phase II Bladder
    - 14 institutions credentialed; 9 patients registered to study; Target Accrual- 98
  - RTOG 0724 : Phase III Stage I/II cervix; IMRT
    - 4 institutions credentialed; 0 patients registered to study; Target Accrual-400
  - RTOG 0815: Phase III Low intermed risk Prostate
    - 5 institutions credentialed; 2 patients registered to study; Target Accrual- 1520
  - RTOG 0822: Phase II IMRT Cape & Oxal in Locally Adv Rectal Cancer
    - 396 institutions credentialed; 70 patients registered to study; Target Accrual – 75
  - RTOG 0825: Phase III Double-Blind RT/TMZ Bev vs RT/TMZ Placebo; 3D-CRT/IMRT for GBM
    - 44 institutions credentialed; 111 patients registered to study; Target
    - Accrual 720

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of October 21, 2009)

- 3D-CRT and IMRT Developing Protocols (25)
  - RTOG 0715: Phase II Study of Recurrent Breast 3DCRT
  - RTOG 0837: Phase II Chemorad vs TMZ & Cediranib in Newly GBM; 3DCRT/IMRT
  - RTOG 0844: Dose Escalation Hypofract RT for Breast
  - RTOG 0838: Phase II IMRT + 5 FU, MMC
  - RTOG 0848: Phase III Resectable Pancreas IMRT
  - RTOG 0912: Phase II Anaplastic thyroid
  - RTOG 0913: Phase I/II Rad001 + TMZ/RT GBM; 3DCRT/IMRT
  - RTOG 0914: Phase II Reirradiation loc adv. H & N
  - RTOG 0916: Phase IIR Sunit/placebo & IMRT Recur GBM
  - RTOG 0918: IMRT + Cis in Locally Advanced Cancer of Uterine Cervix
  - RTOG 0920: *(formerly 0811)* Phase III Intermediate H&N Cancer IMRT + or – C225 (IGRT Optional) *approved by CTEP waiting for drug availability*
  - RTOG 0921: *(formerly 0846)* IMRT + Cis + Avastin in High Risk Endometrial Cancer

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of October 21, 2009)

- 3D-CRT and IMRT Developing Protocols (25) (cont.)
  - RTOG 0926: Phase II Bladder
  - RTOG 0927: Phase III Nasopharyngeal IMRT, Chemo +/- Bev
  - RTOG 0928: Phase II/III Oropharynx (HPV neg), Larynx & Hypopharynx IMRT, Chemo, Cetuximab, A12
  - RTOG 0932: Phase I/ II Pancreas
  - RTOG 0933: Phase II Hippocampal sparing WBRT
  - RTOG 0936: Phase II IMRT, FDR-G Pancreatic Cancer
  - RTOG 0930: Phase II SRS Pituitary Adenoma
  - RTOG 0938: Phase II Hypofrax RT for favorable risk prostate
  - RTOG 1002: Phase II Recurrent Breast
  - RTOG 1005*(formerly 0713):* Phase III IMRT Breast
  - RTOG 1007*(formerly 0940):* Phase III Laryngeal
  - RTOG 1009: Phase III RT with hormones

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of October 21, 2009)

- Proton Developing Protocol (1)
  - RTOG 0922: Phase II Proton Beam & AS in Locally Advanced Prostate Cancer

- Brachytherapy Protocols
  - Active Protocols (3)
    - RTOG 0232: Phase III Comparing Combined External Beam Radiation & Transperineal Interstitial Permanent Brachytherapy with Brachytherapy alone (IMRT added 6/2005)
      - 85 institutions Brachytherapy credentialed (96 IMRT); 471 patients registered to study; Target Accrual – 1520

RTOG Headquarters Report (cont.)

RTOG Protocols supported by the ATC (as of October 21, 2009)

- Brachytherapy Protocols (cont.)
  - RTOG 0413/NSABP B39: Phase III Study of Whole Breast RT versus Partial Breast Irradiation
    - 613 institutions credentialed (462 3DCRT, 326 Mammosite, 56 Multi-Cath); 3486 patients registered to study (1270 3DCRT, 368 Mammosite, 96 Multi-Cath, 1752 WBI)
  - RTOG 0526: Sequential Cohort Phase II trial of Two Dose Levels of Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent Prostate Adenocarcinoma following External Beam Radiotherapy
    - 162 institutions credentialed; 22 patients registered to study; Target Accrual – 96

Brachytherapy Protocols Developing (1)

RTOG 0816: Phase II HDR Brachy Prostate

RTOG Headquarters Report (cont.)

IGRT in RTOG Protocols (as of October 21, 2009)

IGRT Protocols (10 = 2 Closed; 6 Open; 2 Development)

- Lung
  - RTOG 0236: Phase II Study of Extracranial Stereotactic Radioablation in Treatment of Patients with Medically Inoperable Stage in NSCLC
    - 9 institutions credentialed; 10 Pending; 59 patients registered to study; Target Accrual – 59 (study closed, data analysis continues)
  - RTOG 0618: Phase II SBRT for Patients with Operable Early State NSCLC
    - 21 institutions credentialed; 20 patients registered to study; Target Accrual – 33
  - RTOG 0617: Phase III High Dose 3DCRT in (Taxo/Cis) NSCLC
    - 215 institutions credentialed; 163 patient registered to study; Target Accrual – 512
  - RTOG 0813: Phase I SBRT Inoperable NSCLC; IGRT
    - 19 institutions credentialed; 5 patients registered to study; Target Accrual – 94
  - RTOG 0915: Phase II SBRT Inoperable NSCLC; IGRT
    - 1 institutions credentialed; 0 patients registered to study; Target Accrual- 88

RTOG Headquarters Report (cont.)

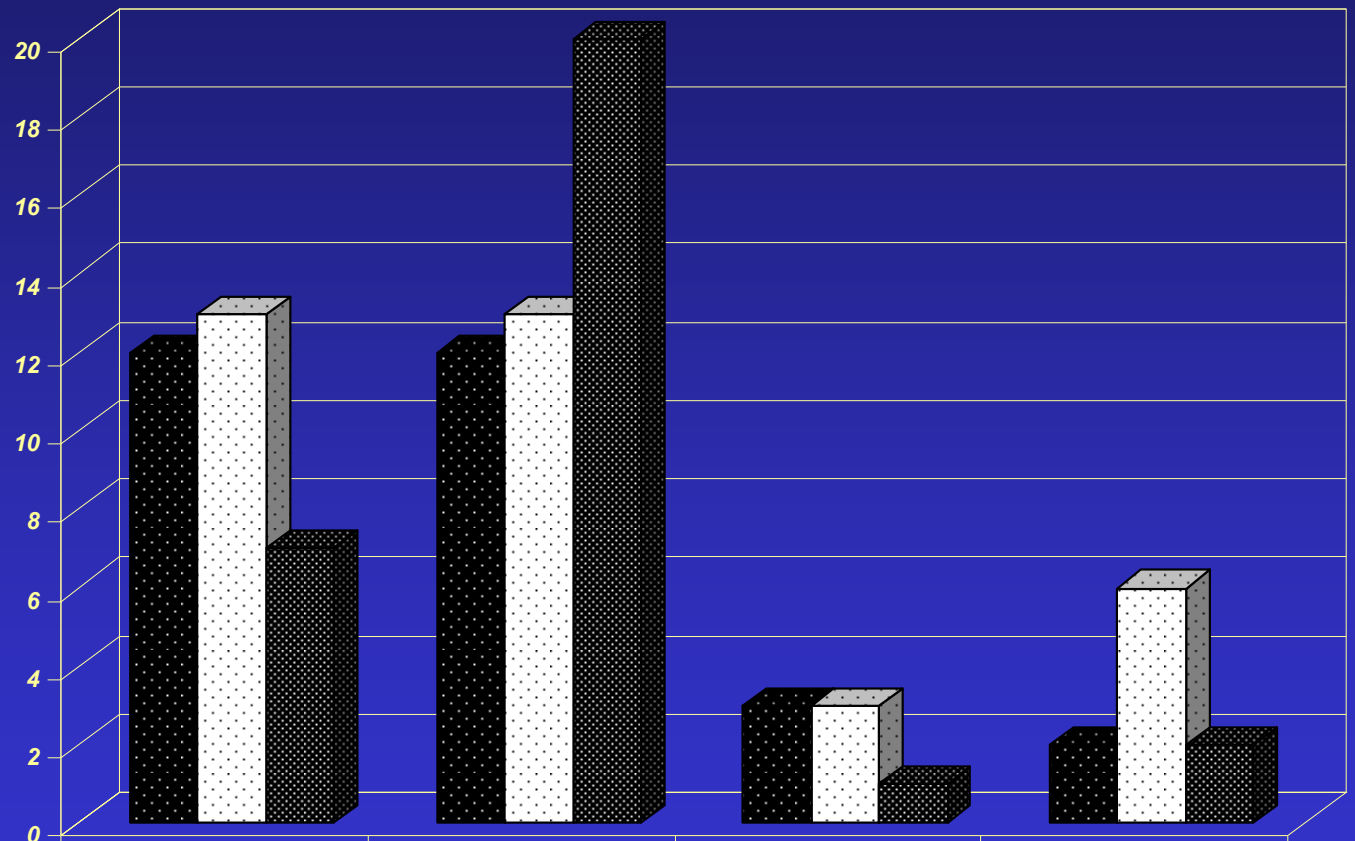
IGRT in RTOG Protocols (as of October 21, 2009)

- Liver
  - RTOG 0438:Phase I Trial of Highly Conformal Radiation Therapy for Patients with Unresectable Hepatobiliary Cancer with Liver Metastases
    - 3 institutions credentialed; 2 Pending; 24 patients registered to study; Target Accrual – 18 (study closed, data analysis continues)
  - RTOG 0935: Phase II SBRT IGRT Hepatocellular CA (Developing)
- Sarcoma
  - RTOG 0630: Phase II IGRT Large Size Soft Tissue Sarcoma
    - 23 institution credentialed; 42 patient registered to study; Target Accrual – 102
- H&N
  - RTOG 0920: (formerly 0811) Phase III Intermediate H&N Cancer IMRT + or – C225 (IGRT Optional) (Developing)
- Spine Mets
  - RTOG 0631: Phase II Stereotactic Radiosurgery for Spine Mets)

    -1 institution credentialed; 13 in the process; 0 patients registered to study; Target Accrual –Phs II 43 Phs III 240

RTOG Headquarters Report (cont.)

ALL PROTOCOLS



	3D-CRT	IMRT	Brachytherapy	IGRT
Closed	12	12	3	2
Active	13	13	3	6
Developing	7	20	1	2

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R. T. Quality Assurance Staff

Back Row L/R: Lorraine Quarles, Jennifer Presley, Denise Manfredi, Tammy McGlade
Front Row L/R: Nancy Linnemann, Betty O'Meara, Julie McIlviane, Joanne Hunter

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ATC Meeting Schedule

- Bi-weekly teleconferences are held on Friday for RTOG/ITC/RPC Specific issues. (Monthly RTOG 0522 Protocol Update call)

- ATC meeting at the RTOG Semi-Annual Meeting in Tampa, Florida January 14, 2010

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RTOG Medical Physics

- RTOG 0848: Phase III Pancreas - EORTC participation
- RTOG 0724: Phase III Cervix - International participation
- RTOG 0930: Phase II SRS Pit Adenoma – Gamma Knife submission

- Lung Phantom irradiations- Modern dose algorithms (convolution)
  - Respiration Control
- Core Lab Facility- RTOG HQ
- Prescription Template for RTOG Protocols
- Protons

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RTOG - ATC Year 11 Plan

- Service
  - Continue service work with RPC & ITC in QA process for RTOG protocols utilizing advanced technologies, in particular providing protocol compliance QA (PCQA) review
    - Roll out new tools for protocol review
    - Develop procedures for remote review using new tools
- Coordination/Standards
  - Develop methodology for writing uniform prescriptions for all disease sites and treatment situations
  - Initiate Adaptive Radiation Therapy (ART) Protocols
  - Develop/present to ATC protocol templates for studies using gating or tracking for respiration control

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RTOG - ATC Year 11 Plan

- New Technologies –Intensity Modulated Arc Therapy (IMAT)
  - Requires recredentialing
- All heterogeneity corrections must be performed with modern calculation algorithms
- Continue developing consensus guidelines for different aspects of protocols (e.g., prescriptions, contouring, SRS)
- Develop guidelines for the use of *dose painting* treatment delivery techniques
- New Technologies – Particle Beams
- Develop Guidelines for Protocol Design

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RTOG – Uniformity of Prescriptions

- The prescription is an essential part of any protocol that includes RT
- The RTOG prescription includes Compliance Criteria aimed at guaranteeing optimum treatment plans
- The RTOG prescription includes critical structure dose limits
- The RT community currently does not have an accepted standard for writing prescriptions
- SRS, IMRT, 3D-CRT and 2D prescriptions are typically written with completely different techniques
  - many RTOG protocols include more than one of these techniques
- Different cooperative groups handle the prescription part of the protocol differently

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RTOG – Uniformity of Prescriptions

6.1.5 Normalization of the treatment plan will cover 95% of the PTV with the prescription dose. The minimum PTV dose must not fall below 95% of the prescription dose.

6.7 Compliance CriteriaSee Section 6.1.4 for radiation dose compliance criteria

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6.1.6 Variation of dose prescription

6.1.6.1 No deviation: ≥ 99% of the PTV receives ≥ 93% of the prescribed dose, and a contiguous volume of no more than 2cc inside PTV exceeds 20% of the prescribed dose.

6.1.6.2 Minor deviation: Deviations of this magnitude are not desirable, but are acceptable. Coverage that is equal to 93% of the prescribed dose and falls between 99% and 95% of the PTV, or a contiguous volume of no more than 2cc in side the PTV exceeds 20-25% of the prescribed dose.

6.1.6.3 Major deviation: Doses in this region are not acceptable. More than 1 cm3 of tissue outside the PTV receives ≥ 120% of the prescribed dose, or 93% of the prescribed dose falls below 95% of the PTV, or a contiguous volume of no more than 2cc inside the PTV exceeds 25% of the prescribed dose.

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RTOG – Uniformity of Contouring

- The contouring of the target(s) and nearby critical is an essential part of any protocol that includes RT
- Variation in contouring is equivalent to a variation in prescribed dose
- Many different techniques are used by the RTOG to guarantee precise contouring
  - General education sessions at RTOG meetings and elsewhere
  - Detailed information placed in particular protocols
  - Test cases that must be completed to credential institutions before starting to accrue patients to a particular protocol or category of protocol
  - Rapid reviews by the PIs for one or more patients entered on protocol
  - Credentialing of individual investigators to participate on a protocol
- Variation of contouring can lead to a "deviation unacceptable" that is often detected only after the protocol has closed

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That's All Folks!

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IMRT Hormonization

- Define IMRT
- Some credentialing needed
- Phantom irradiation recommended for some new advanced technologies
- Effectiveness Research needed to compare phantom irradiation and benchmark approach

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IGRT Harmonization

- Define IGRT
- Protocols that reduce margins with IGRT
- Protocols must include instructions
- Questionnaire must include dose estimate
- Universal Isocenter-Coincidence test required
- Verification test recommended for reduced margins and hypofractionation

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IGRT in RTOG Protocols

- Protocol IGRT specifications
- IGRT questionnaire
- Phantom Irradiation
  - Treatment units that do not include a robotic couch
  - Test to evaluate the performance of robotic couches with pitch and roll capabilities
- Image Registration Software Tests
- Dose consideration with IGRT

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Phantom Irradiation

- The steps in the process of Phantom Irradiation:
  1. Image the phantom using a diagnostic quality CT scanner
  2. Generate different treatment plans for each marker. Each of the three plans should have three beams hitting a particular marker. The field sizes should be on the order of a 2.0 cm square or circle. The plans should be generated with the assumption that the phantom will NOT be moved to target each marker. Instead, for the CyberKnife unit, the accelerator must be moved to the next marker or, for isocentric units, the MLC must be adjusted for targeting each marker.

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Phantom Irradiation

3. Move the phantom from the CT-Sim unit to the treatment unit and position it to match the setup used during the CT procedure as closely as possible. For treatment units that have a mechanical isocenter, set the central marker as near to this position as possible. For treatment units that do not have a physical isocentric unit, use the approximate isocenter of the imaging system to position the marker.
4. Introduce small setup errors (i.e., central marker relative to the physical or the imaging isocenter) by using the linear motions and turntable rotation of the patient support system.

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Phantom Irradiation

5. Use the in-room image-guided capability to re-image the phantom.
6. Register the simulation and in-room datasets to determine magnitude of setup errors.
7. Use these setup errors to correct positioning of phantom.
8. Using one of the treatment plans generated in step #2, irradiate the first of the multi-field plan with a small piece of radiochromic film placed on the exit side of the phantom. The film should be marked to show its orientation. Remove this film.

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Phantom Irradiation

9. Select the second field of this plan and reposition the accelerator. Place a second film on the exit side of the beam and irradiate. Remove this film and repeat the process for the third field.
10. Without moving the phantom, repeat the entire process described above for the second and third markers.
11. This procedure results in 8 film images that can be analyzed to determine the ability of the IGRT system to position treatment fields relative to points with known coordinates positioned in space.

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