QARC
QUALITY ASSURANCE REVIEW CENTER

ATC AdvancedTechnologyConsortium
Providing support in quality assurance and data management for radiation therapy clinical trials

QARC-ATC Activities

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UMass Memorial Medical Center

ATC Evaluation Committee Meeting
New Orleans, LA
Jan. 15, 2009

QARC Background

The Quality Assurance Review Center (QARC) is a research program within the University of Massachusetts Medical School providing radiotherapy quality assurance and diagnostic imaging data management services. QARC is a nationally and internationally recognized program serving the National Cancer Institute (NCI) sponsored cooperative groups and the pharmaceutical industry for over three decades.

QARC manages/archives data and provides RT and/or Imaging reviews on over 130 active protocols for:

ACOSOG

CALGB

COG

ECOG

PBTC

SWOG and

industry studies.

QARC Archive

The QARC archive contains:

- Data from more than 350 protocols
- 45,000 protocol cases (45% pediatric) from 1,400 participating institutions
- More than 40,371 diagnostic studies encompassing 9 million images files.
- MAX, QARC's database, includes functionality that links demographic and clinical protocol patient data to the diagnostic imaging and RT objects.

ATC-QARC

ATC provides the mechanism to develop and foster collaborative research among the RT QA centers. This collaboration benefits each RT QA Center and the Entire Clinical Trials Enterprise.

- ATC has helped QARC expand digital review and bring acquisition of digital objects to worldwide attention.
- ATC facilitates the standardization and harmonization of methodologies for RT Facility credentialing.
- Uniform acquisition strategy will permit a uniform review of digital imaging and RT objects through all clinical trials
- QARC in turn has the responsibility to share its experience and expertise in digital imaging acquisition with the ATC.

QARC-ATC

- Credentialing
- Digital RT Data Acquisition and Review
  - Remote Review Tool (RRT)
  - Computational Environment for Radiotherapy Research (CERR)
- NCI Initiatives
  - Virtual Imaging Evaluation Workspace (VIEW)
  - cancer Biomedical Informatics Grid (CaBIG)

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ATC Credentialing Accomplishments

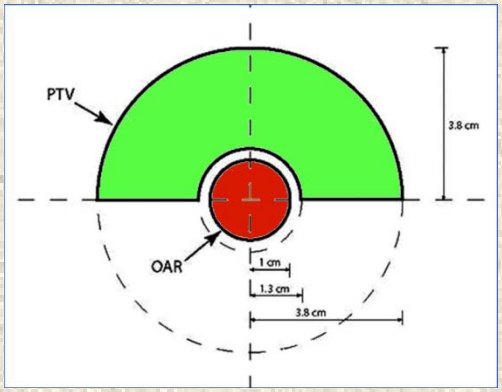
Development of uniform guidelines for advanced technology treatment modalities:

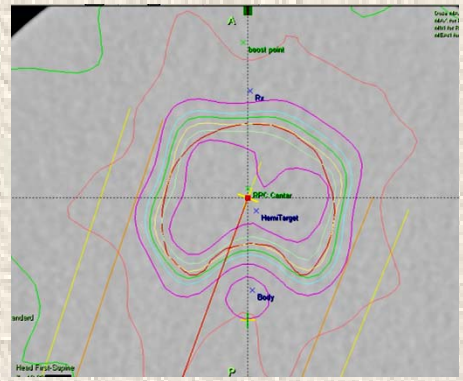
- ATC Guidelines for the Use of IMRT (including Intra-Thoracic Treatments)
- Guidelines For The Use Of Proton Radiation Therapy In National Cancer Institute Sponsored Cooperative Group Clinical Trials

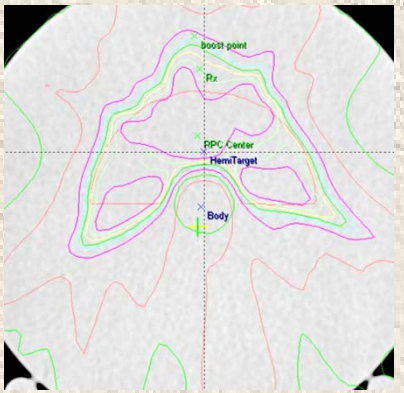
ATC Credentialing Accomplishments

- <u>Reciprocity of IMRT credentialing</u> among cooperative groups

  RPC phantoms and/or QARC benchmark





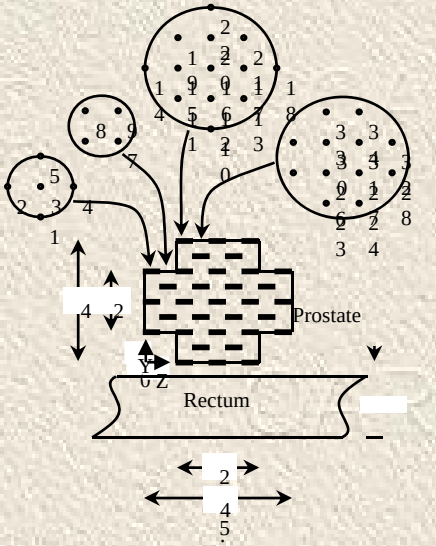


ATC Credentialing Accomplishments

- Uniform credentialing for prostate seed implants

  RPC (RTOG) and QARC (ACOSOG)

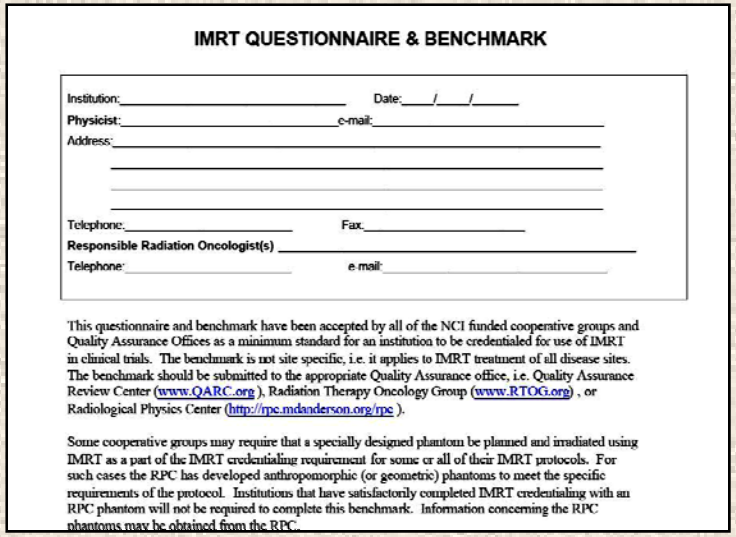
  Developed benchmark case with acceptability criteria



- Unification of informational forms

  Prostate seed implant facility survey and questionnaire

  Questionnaire for IMRT



IMRT QUESTIONNAIRE & BENCHMARK

Institution:_____ Date:____/____/_____

Physicist:_____ e-mail:_____

Address:_____

_____

_____

_____

Telephone:_____ Fax:_____

Responsible Radiation Oncologist(s) _____

Telephone: e-mail:

This questionnaire and benchmark have been accepted by all of the NCI funded cooperative groups and Quality Assurance Offices as a minimum standard for an institution to be credentialed for use of IMRT in clinical trials. The benchmark is not site specific, i.e. it applies to IMRT treatment of all disease sites. The benchmark should be submitted to the appropriate Quality Assurance office, i.e. Quality Assurance Review Center (www.QARC.org), Radiation Therapy Oncology Group (www.RTOG.org), or Radiological Physics Center (http://rpc.mdanderson.org/rpc).

Some cooperative groups may require that a specially designed phantom be planned and irradiated using IMRT as a part of the IMRT credentialing requirement for some or all of their IMRT protocols. For such cases the RPC has developed anthropomorphic (or geometric) phantoms to meet the specific requirements of the protocol. Institutions that have satisfactorily completed IMRT credentialing with an RPC phantom will not be required to complete this benchmark. Information concerning the RPC phantoms may be obtained from the RPC.

ATC Credentialing QA Committee (ACQAC)

Mission: To help the ATC promote uniformity in credentialing and quality assurance criteria for advanced technology clinical trials across cooperative groups and QA Centers supported by the National Cancer Institute.

Members:

David Followill (Co-chair)	RPC
Marcia Urie (Co-chair)	QARC
Jim Galvin	RTOG
Bill Straube	ITC

ACQAC will assist the ATC in realizing its vision and achieving its goals by

- Reviewing existing credentialing/QA tests and criteria used by the major QA Centers/Cooperative Groups
- Assessing clarity and correctness of credentialing procedures
- Developing and/or reviewing new protocol credentialing procedures/QA criteria for emerging technologies

With the goals of:

- Uniform credentialing requirements consistent across cooperative groups
- Credentialing processes that are recognized among all QA centers and all groups
- Uniform dose prescription and dose uniformity criteria across all groups

ACQAC – Projects for Consensus

- Determine importance of RPC TLD independent dose measurement requirement (and if important, at what frequency)
  - RPC (D. Followill) has drafted a report analyzing TLD's

    (demonstrating their importance)
  - Literature search

- Harmonization with EORTC

  M. Urie in contact with Akos Gulyban

  Quality Assurance Manager for Radiotherapy
  EORTC European Organization for Research and Treatment of Cancer

  attending this meeting

  initial discussion of unification of facility questionnaire

ACQAC – Projects for Consensus

- Harmonization of IMRT Credentialing Requirements

  J. Galvin drafted “RTOG” position

  RPC and QARC edited for their positions

  Consensus version under discussion

- Harmonization of IGRT Credentialing Requirements

  Under discussion

  IMRT credentialing harmonization will facilitate consensus

ACQAC – Projects for Consensus

- Harmonization of Dose Prescription and Dose Uniformity

  for all protocols among all groups

  M. Urie has compiled representative examples from

  current RTOG, COG, ECOG, CALGB and SWOG protocols

- Development of web-based review tool for all QA centers

  Probably **CERR**

  Identify how each QA center would use CERR

  What are problems with current version

  Provide feedback to J. Deasy's group

Digital Data Acquisition

•The ATC has been instrumental in establishing the capability to perform digital RT data review at QARC.

•In 2004 the Remote Review Tool was installed remotely at QARC by the ITC (Walter Bosch and John Matthews).

•Several changes were made to the Remote Review Tool at that time to accommodate QARC's needs.

•In 2005 FTP server software and account maintenance tools were installed at QARC by the ITC (Walter Bosch).

•In 2007 the ITC converted QARC's FTP server software to secure FTP.

Digital Data Acquisition

•QARC is now using both the Remote Review Tool and CERR for digital RT data review.

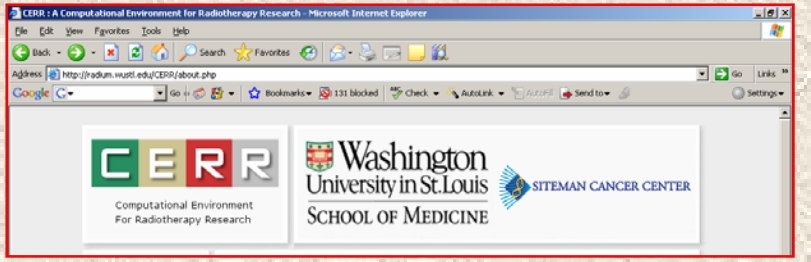
•Submission of data by either SFTP or CD is supported. 227 institutions have sFTP sites set up at QARC.

•Digital plans for over 800 patients have been received.

•ITC worked diligently so that nearly all treatment planning vendors now export plans in RTOG or DICOM RT format.

•As new studies are activated the requirement to submit all RT data in digital format will become the standard.

Use of CERR at QARC



•QARC began using CERR for digital RT reviews in 2007 for visualization of anatomy in sagittal and coronal views.

•CERR has been extensively customized for use at QARC.

•Many of these modifications have been incorporated into the downloadable version of CERR, which continues to be under development for use by all ATC members.

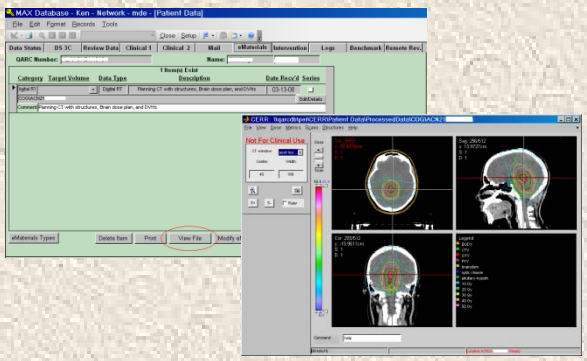
•A network concurrent license for Matlab enables use of CERR by all users on the local network.

•Use of CERR is enabled remotely by connection to a terminal server through a web browser.

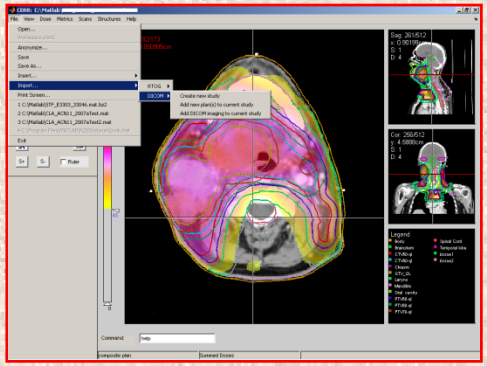
Use of CERR at QARC

Modifications and enhancements made to CERR for QARC use include:

- A command line to launch a CERR study from the patient's record in the QARC database



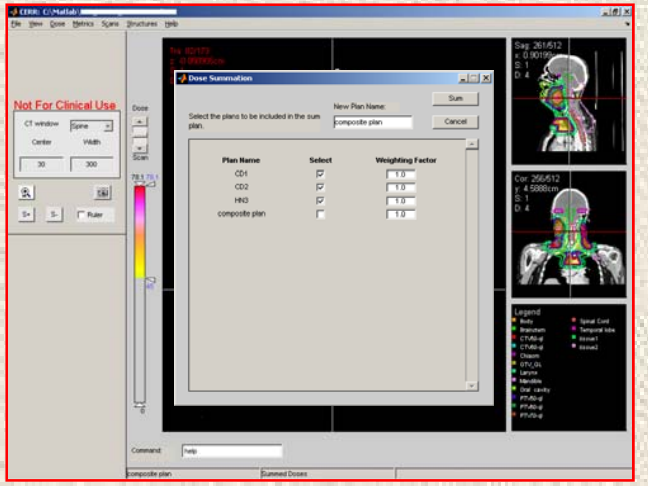
- Import of additional plans to an existing study (subsequent phases of treatment and/or modified plans)

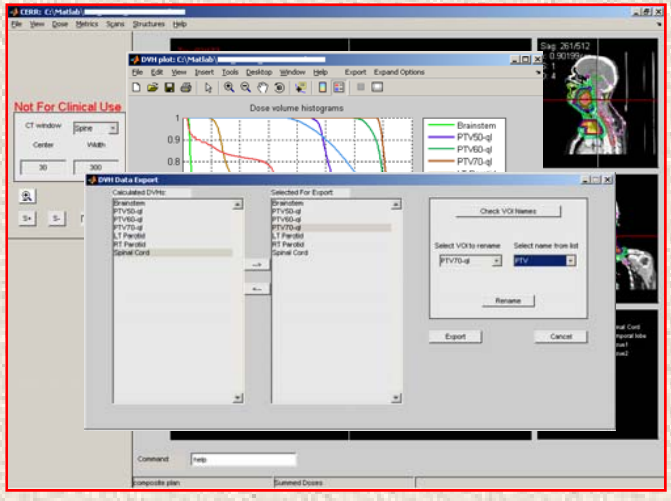


Use of CERR at QARC

Modifications and enhancements made to CERR for QARC use include:

- Improvement in import speed for DICOM RT
- Multiple consistency checks applied during the import process and when changes are made within the viewer
- Dose summation of multiple (>2) dose distributions
- An export function to export DVH data to a delimited text file for further analysis





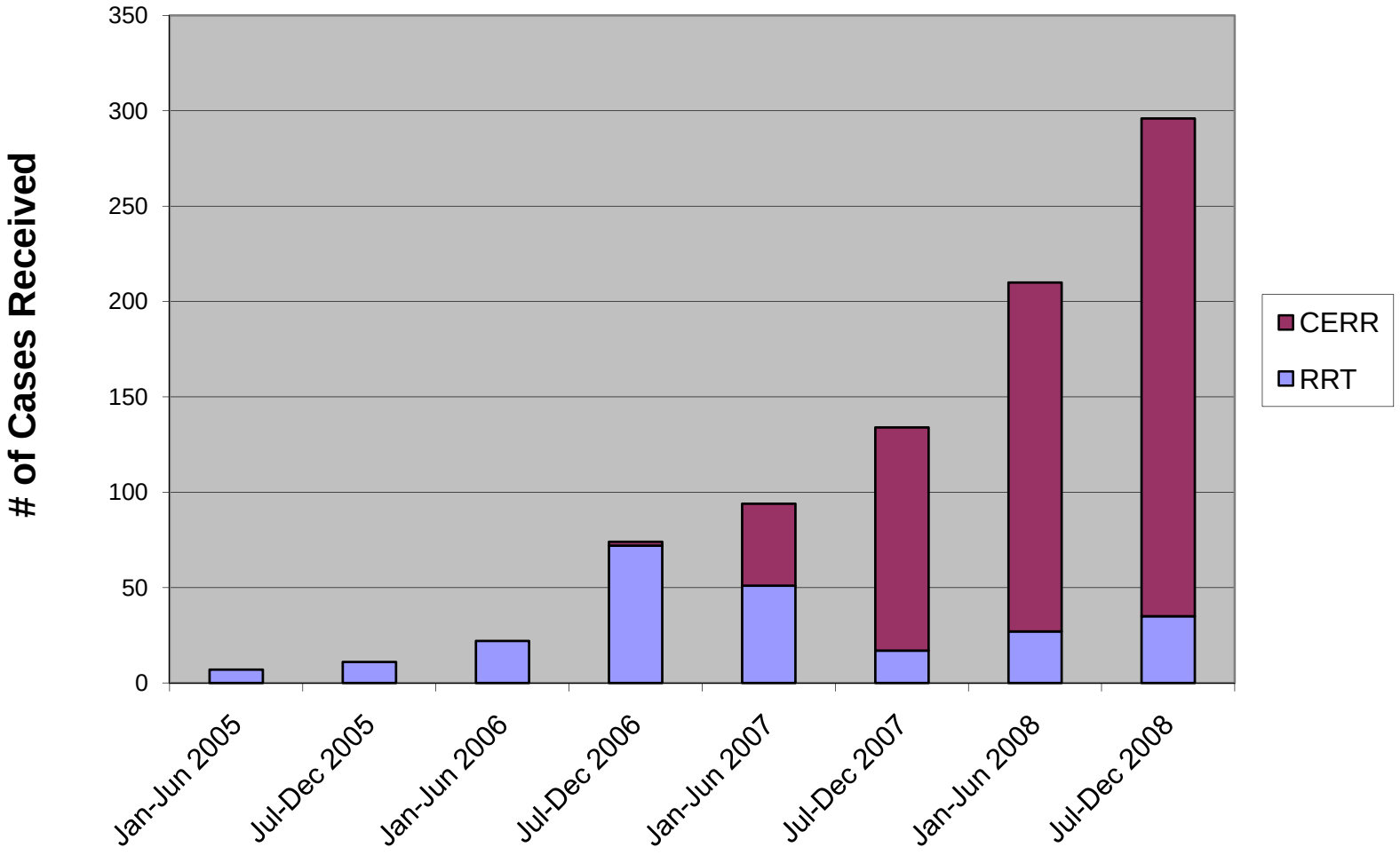
Use of CERR at QARC

- More than 600 protocol cases and 200 benchmark cases have been imported into CERR.
- Studies from 14 planning systems have been successfully imported into CERR.

Use of CERR at QARC

Full data sets from 14 planning systems have been successfully imported into CERR	
DICOM RT	**RTOG**
Eclipse	Pinnacle
Variseed	XiO
Plato	Theraplan Plus
XiO	Corvus
Oncentra Masterplan	UMPlan
Pinnacle	
TomoTherapy Hi-ART	
Helax	
IsoGray	
Konrad	
Memorial Planning System	

QARC Digital RT Data



VIEW

- **Virtual Imaging Evaluation Workspace (VIEW) in Cooperative Groups**
- **Collaboration:**
  - **ACRIN**
  - **CALGB Image Core Lab**
  - **QARC**

NCI RFP

- Establish a consortium to provide imaging core laboratory services to the NCI-sponsored cooperative groups, and, if necessary, other NCI-sponsored clinical trial programs
- Develop an inter-operative IT infrastructure across the network for collection, distribution and archiving of images obtained on NCI-sponsored trials that utilize VIEW. This IT infrastructure will be 21 CFR Part 11 compliant and caBIG compatible.
- Develop standard operating procedures for acquisition and assessment of imaging endpoints in cancer clinical trials and an approach to standardizing newer imaging markers. This includes the development of standardized quality assurance approaches and the establishment of quality performance metrics.

The VIEW Consortium

- ACRIN's entire mission is dedicated to imaging clinical trials and has developed a comprehensive imaging core laboratory
- QARC has been providing imaging core laboratory support to cooperative groups for radiation therapy planning and more recently imaging core services for 25 years
- CALGB has a strong imaging committee with expertise in functional anatomic imaging and has an imaging core laboratory at Ohio State University

All Have Well-Developed Imaging Core Laboratory Standard Operating Procedures

ACRIN™ American College of Radiology Imaging Network

CALGB Tomorrow's Cancer Treatments Today

The Ohio State University

QARC Quality Assurance Review Center

VIEW Aims

- Develop a standardized approach to credentialing facilities that perform imaging exams according to the VIEW standards.
- Assist clinical trial organizations in the development of an imaging charter that is acceptable to the trial sponsors and FDA.
- Advance the science of imaging biomarker development: explore alternative imaging analysis, alternative imaging approaches, and establish databases that can be mined for testing new approaches.

Imaging Protocol Development

- Imaging endpoint addresses clinical / mechanistic question
- Instrumentation specified
- Acquisition protocol specified and reproducible
- Analysis standardized
- Data “quality” validated

VIEW Status

- First annual VIEW Meeting: June, 2008.
- First protocol utilizing VIEW: NCCTG (N0723 the MARVEL Trial-A Phase III biomarker validation study Second-Line Therapy in Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) Randomized to Pemetrexed vs Erlotinib) opened on November 1, 2008 with an expected accrual of 1197 patients. Coordinated by NCCTG and available to all groups on CTSU.
- First VIEW meeting with FDA: November, 2008.
- Second protocol utilizing VIEW: RTOG – 0825 A phase III double blind placebo controlled trial of conventional concurrent Chemoradiation and adjuvant Temozolomide plus Bvacizumab versus conventional concurrent Chemoradiation and adjuvant Temozolomide in patients with newly diagnosed glioblastoma is under discussion.

caBIG

cancer Biomedical Informatics Grid

- QARC is working with caBIG to adopt tools as they become available on the caBIG grid.
- The unique functionality of the QARC database as it displays both imaging and RT objects in a side by side format one click from each other is recognized by caBIG.
- It is also recognized that the QARC database can easily be adapted to display digital pathology objects.
- Eliot Siegel MD and Paul Mulhern of the workspace are promoting this activity. In collaboration with Joel Saltz MD, QARC is putting the infrastructure in place to build a cache version of the database, which will be distributed, to members of VIEW and ATC.

Bibliography

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