Advanced Technology Radiation Therapy Clinical Trials Support (ATC)

- ATC concept dates from April 1992 when 3DQA Center was established at WU-St. Louis to provide QA for support of RTOG 3DCRT trials.
- Two NIH funded ATC Centers created in 1998 (3-year grant)
- Since 2001, grant (5-year) functions as QA Consortium capitalizing on existing infrastructure and strengths of national QA programs

Subcontracts allow for close coordination of resources and methods.

- Image-Guided Therapy Center (ITC – Washington University in St. Louis and UC Davis)
- Radiation Therapy Oncology Group (RTOG)
- Radiological Physics Center (RPC, M.D. Anderson Cancer Center)
- Quality Assurance Resource Center (QARC)
- Resource Center for Emerging Technologies (RCET – Univ. Florida Gainesville)

NATIONAL CANCER INSTITUTE

Radiation Therapy Trials - Quality Assurance:

- patient safety
- adherence to protocol constraints
- uniformity of patient treatments
- efficient review of patient data

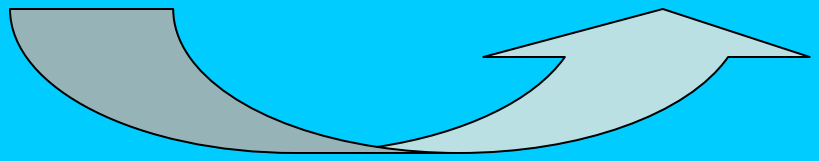
CTEP supported CLINICAL TRIAL QA CENTERS

RTOG, Philadelphia (RTOG)

QARC, Providence (COG, CALGB, SWOG, ECOG, ACOSOG, - - -)

RPC, MD Anderson (NSABP, GOG and physical dose QA for ALL groups)

Review item:	**Conventional**	**Advanced tech trials**
chart:	Post Tx	Real-time and pre-Tx
images:	Few – hard copy- largely 2D	Gbytes of digital – multi modality
study chairs:	Travel to QA center	Remote review by internet
archives:	Hard copy- difficult searches	Digital full datasets



ATC cooperative agreement

developmental: ITC, RCET

implementation: RTOG, QARC, RPC

NATIONAL CANCER INSTITUTE

OVERALL GOALS

- To facilitate the conduct of NCI sponsored advanced technology radiation therapy clinical trials that require digital data submissions.
- Effort includes coordination of QA activities,image/RT digital data management, RT QA, and clinical trials research & developmental efforts.
- Expectation that advanced medical informatics can facilitate education, collaboration, and peer review.
- Ultimate goal is to improve the standards of care in the management of cancer by improving the quality of clinical trials medicine.

NATIONAL CANCER INSTITUTE

ATC Challenges/Opportunities

- ✓ **RT Protocols increased use of:**
  - **PET (quantitative) data import & image fusion QA**
  - **Image-Guided RT (EPID, MV and kVp Cone beam CT, Helical Tomotherapy megavoltage CT)**
  - **4-D CT (several 100 MB)**
  - **Adaptive Radiation Therapy (Daily Confirmation/Adjustment using On-Board Imaging)**
  - **Protons (physics and target volume issues)**

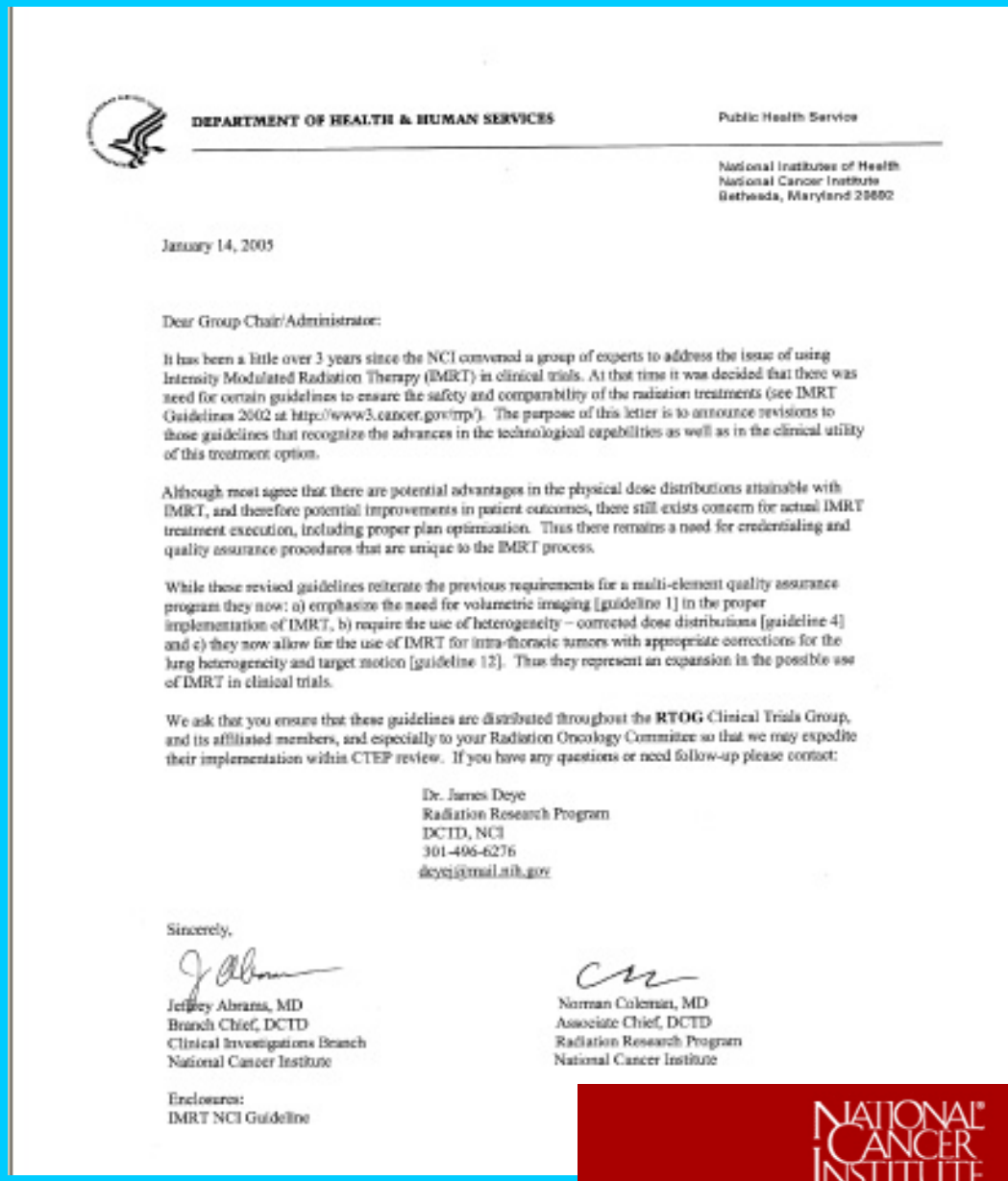
- ✓ **Incorporate caBIG compliant status**

- ✓ **Extend existing ATC capabilities -**
  to more cancer disparities sites (CDRP), and
  to more community cancer treatment sites (eg. CTSU & NCCCPs)

- ✓ **Continue to work with International sites such as EORTC, NCIC, JCOG and TROG**

NCI IMRT PROTOCOL REQUIREMENTS

- **2002: guidelines for IMRT use in clinical trials were established to ensure the safety and comparability of these radiation treatments.**
- **2005: NCI announced revisions in these guidelines allowing use of IMRT for intra-thoracic treatments.**
- **2006: specific guidelines for use of IMRT for intra-thoracic treatment protocols with respiratory gating**



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

January 14, 2005

Dear Group Chair/Administrator:

It has been a little over 3 years since the NCI convened a group of experts to address the issue of using Intensity Modulated Radiation Therapy (IMRT) in clinical trials. At that time it was decided that there was need for certain guidelines to ensure the safety and comparability of the radiation treatments (see IMRT Guidelines 2002 at http://www3.cancer.gov/rtp/). The purpose of this letter is to announce revisions to those guidelines that recognize the advances in the technological capabilities as well as in the clinical utility of this treatment option.

Although most agree that there are potential advantages in the physical dose distributions attainable with IMRT, and therefore potential improvements in patient outcomes, there still exists concern for actual IMRT treatment execution, including proper plan optimization. Thus there remains a need for credentialing and quality assurance procedures that are unique to the IMRT process.

While these revised guidelines reiterate the previous requirements for a multi-element quality assurance program they now: a) emphasize the need for volumetric imaging [guideline 1] in the proper implementation of IMRT, b) require the use of heterogeneity – corrected dose distributions [guideline 4] and c) they now allow for the use of IMRT for intra-thoracic tumors with appropriate corrections for the lung heterogeneity and target motion [guideline 12]. Thus they represent an expansion in the possible use of IMRT in clinical trials.

We ask that you ensure that these guidelines are distributed throughout the **RTOG** Clinical Trials Group, and its affiliated members, and especially to your Radiation Oncology Committee so that we may expedite their implementation within CTEP review. If you have any questions or need follow-up please contact:

Dr. James Deye
Radiation Research Program
DCTD, NCI
301-496-6276
deyej@mail.nih.gov

Sincerely,

Jeffrey Abrams, MD
Branch Chief, DCTD
Clinical Investigations Branch
National Cancer Institute

Norman Coleman, MD
Associate Chief, DCTD
Radiation Research Program
National Cancer Institute

Enclosures:
IMRT NCI Guideline

NATIONAL CANCER INSTITUTE

GUIDELINES FOR THE USE OF PROTON RADIATION THERAPY IN NATIONAL CANCER INSTITUTE SPONSORED COOPERATIVE GROUP CLINICAL TRIALS (June 2007)

Before treating with PRT any patients participating in a cooperative group protocol, an institution must be appropriately credentialed for PRT by the QA center designated in the protocol.

Only passively scattered or actively scattered (wobbling) beams shall be employed [1].

The IAEA TRS 398 protocol (available at http://www-naweb.iaea.org/nahu/dmrp/pdf_files/CoPV11b.pd) shall be used for beam calibration [2].

All doses shall be expressed as Cobalt Gray Equivalent (CGE, e.g. 70 CGE) employing a standard RBE of 1.1 with respect to Cobalt-60 [3].

Treatment planning shall be performed on a CT scan obtained with the patient in the treatment position. Correlation between the institutional 'CT treatment planning system Hounsfield Units' (for the specific CT scanners and parameters) and 'relative proton stopping power' must be established at each institution and demonstrated to the satisfaction of the quality assurance center designated in the protocol [4].

Doses will be specified to volumes using standard nomenclature, i.e. GTV, CTV, and PTV. The GTV and CTV shall be identical for protons and photons but in specifying the PTV every protocol that allows PRT must explicitly address issues unique to PRT such as range uncertainties and lateral scatter [5].

Before treating with PRT any patients participating in a cooperative group protocol, an institution shall undergo a site-visit by the Radiological Physics Center (RPC) for conducting measurements and an audit of its proton facility. In addition, the RPC shall conduct annual remote monitoring of the proton calibrations as they relate to clinical trials in which the facility is participating [6].

Every protocol that allows PRT 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 the specific constraints related to the PTV and OAR [7].