



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/rrp/). 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 Deve 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

Enclosures:

IMRT NCI Guideline

Norman Coleman, MD Associate Chief, DCTD

Radiation Research Program National Cancer Institute