**To:** **ATC Steering Committee**

**From:** **J. A. Purdy, Ph.D.**
**ATC Principal Investigator**

**Date:** **September 21, 2004**

**RE:** **Response to ATC Steering Committee Meeting, Washington D.C., March 31, 2004 (received May 7, 2004)**

The ATC wishes to thank the members of the ATC Steering Committee (ATCSC) for agreeing to provide input and review for this important NCI sponsored project. We also thank the ATCSC for it's kind remarks regarding ATC competency in the relevant technologies, and its effectiveness in defining technology needs and working with both users and manufacturers to achieve important goals. Most importantly though are the critical questions and comments raised by the ATCSC. I have listed each question below and provided our response following each question:

1. I would like Dr. Purdy's to state his vision for the accomplishments of the ATC by the end of this grant period.

   **Response:** The ATC Mission statement provide a clear statement of what Dr. Purdy expects the ATC to have accomplished by the end of the current 5-year grant. The ATC will facilitate the conduct of National Cancer Institute sponsored advanced technology radiation therapy clinical trials that require digital data submissions while maintaining patient confidentiality. This effort includes radiation therapy quality assurance, image and radiation therapy digital data management, and clinical research and developmental efforts. We strongly believe that advanced medical informatics can facilitate education, collaboration, and peer review, as well as provide an environment in which clinical investigators can receive, share, and analyze volumetric multimodality treatment planning and verification (TPV) digital data. Our ultimate goal is to improve the standards of care in the management of cancer by improving the quality of clinical trials medicine. At the end of this grant period, we will have met the following objectives: (a) The ATC will be recognized as an educational and developmental resource to the nation's clinical trial cooperative groups and participating institutions for support of advanced technology radiation therapy clinical trials; (b) The ATC will have played a key role in developing electronic data exchange mechanisms (primarily DICOM) of treatment planning and verification (TPV) data between the ATC QA Centers and the protocol participating institutions, and between the ATC members and cooperative group Operations, Statistics, and Data Management Section(s); (c) ATC Methods 1, 2, and 3 will provide robust software tools to facilitate QA reviews by RTOG, QARC, and RPC of TPV data submitted by institutions participating in cooperative group clinical trials (both pediatric and adult) that utilize advanced technologies, including 3DCRT, IMRT, and brachytherapy. These tools will be web-based remote-review tools that allow for the efficient review of centrally located image-based data by reviewers not co-located with these data; (d) The ATC will have in place an archival TPV database for the advanced treatment modalities that can be linked with the cooperative group's clinical outcomes database; (e) The ATC will be sought after by all cooperative groups to provide

expertise in the areas of protocol design, credentialing, monitoring, and analysis for new clinical trials that utilize advanced technologies and require digital data submission, with the intent to ensure uniformity of guidelines; (f) The ATC will have been acknowledged by participating cooperative groups in the role they played in facilitating protocol credentialing, digital data submissions, QA reviews, and outcome analysis. We strongly believe that by the end of this grant period there will be an active ATC presence within all cooperative groups with recommendations established for uniform data collection for radiation therapy objects. Recommendations for image submission, both linked and independent of radiation therapy, will be established with pathways identified for uniform image data transfer.

2. The ATC must make a more detailed list of near term objectives than just the 4 points mentioned at the meeting. These should be prioritized. Most importantly, a timeline for completion of these objectives is required. One objective that needs to be specifically addressed is the handling of data uploaded. Currently, manual sorting and other manipulation are required which is not practical especially for rapid review protocols. Also, be specific about the phase in of method 2 and the phase out of method 1.

   **Response:** An ATC Priority List and ATC Tools Status Report is now maintained on the ATC website. The top priority for the IT Task Group is the development of a Linux platform for the receipt and QA of digital data at QARC and RPC. This platform is intended to provide these centers with more efficient access to the volumetric imaging and dosimetry data currently submitted using ATC Method 1. Drs. Bosch and Matthews are developing a prototype RRT server and DICOM/RTOG data import tool for use at the ATC/AAPM/NEMA DICOM Demonstration at the AAPM 2004 annual meeting. Dr. Purdy is pursuing licensing arrangements with CMS to allow distribution of proprietary components of this software within the members of the ATC.

3. Specifically how will the ATC encourage user input for the further development of the software tools for data upload and review?

   **Response:** User input is an important aspect of the monthly conference calls and the meeting at RTOG every six months. This will be the recommended vehicle to continue to address changes needed in ATC Method 1. RTOG and RPC have provided good feedback to the ITC regarding the Remote Review Tool. Once ATC Method 2 is actually used for real protocol patient data review by RTOG, RPC, and QARC, feedback on tool features and new tools will be provided by the QA Centers.

4. What is the specific plan to educate CRAs and others about how to perform image an RT data uploads to ATC? This should not be left to each center's staff to figure out. I would suggest a letter to the facility PI and CRA in charge introducing the ATC and its mission, describing the resources ATC provides, and why electronic data submission is important. A statement regarding the security and anonymizing of data should be included. This should be followed with a tutorial on CD that can be sent to the CRAs or physics staff.

   **Response**: We now provide a presentation to CRAs at each RTOG semi-annual meeting regarding digital and hard copy data submission to the ATC QA centers. In addition, each ATC member group has well-established relationships with institutional CRA. The most

efficient use of time may be to focus education efforts on the CRA staff of ATC members who in turn would be responsible for re-distribution of information to respective cooperative groups and institutional CRA staff.

5. An important mission of the ATC is to facilitate future outcomes research. The ATC should develop a strategy for this rather than taking the attitude that each national resource database is controlled by its owner and is not available to the ATC. This strategy should include a dialog between the various resource centers about common data elements. The timeline developed for this should include a date for testing the connectivity between different databases.

   **Response:** We believe the current ATC approach is the proven pathway for success. The cooperative groups own the individual protocol data and it is not the role of the ATC to challenge this. If this is something NCI wants, they should give a clear directive. We are cooperating with individual researchers request by being supportive in their request and encouraging the cooperative group to agree. An example is the work we have done in support of Dr. Sue Tucker and Dr. Joe Deasy's RO1 applications.

6. There appears to be duplication of efforts between WebSys and QARC's dicommunicator for upload to QARC of images. QARC's website states that dicommunictor is the preferred method for submission. A clear statement needs to be made indicating what service a user should employ when uploading RT-relevant images for archival and review by QARC.

   **Response:** Dicommunicator was developed in 1999 as a project of the diagnostic imaging committee of COG to facilitate electronic image transfer to QARC in order to perform clinical and outcome research for the diagnostic imaging committee. A diagnostic radiologist (Keith White) developed and initiated this project with QARC in collaboration with investigators from the United Kingdom. This was one of the signature presentations made to the NCI review committee for the last competitive renewal for QARC in May of 2000. QARC uses Dicommunicator for many facets of its operation including directly entering DICOM images on CD into its database for viewing electronic images as well as its primary role for direct electronic image transfer from institutions to QARC. The COG funds a Dicommunicator operations individual at QARC to facilitate this research endeavor. QARC thus can enter this data into the database without an intermediary step and link the images to the RT objects dataset housed in the database. QARC's experience with Dicommunicator will help facilitate implementation of Method 3 strategies for ATC. The majority of institutions prefer to forward images to QARC via CD at this time. Dicommunicator can facilitate this process. QARC shares all of its information and experience with Dicommunicator with ATC members. It is not viewed as a competitive project. It is viewed as a project that helps individual institutions forward diagnostic images for QA in as facile a manner as possible for pre/on treatment review. It likewise serves as a vehicle for radiology research. It does not handle data formats other than DICOM; radiation therapy objects are not addressed with this software. At this time institutions prefer to forward information to QARC in heterogeneous formats, therefore QARC feels the need to accept data in diverse formats which can than enter our database for uniform presentation. This experience will be very useful for the development of Method 3 (capture scanned and screen captured images) modes of transfer.

7. Provide electronic forms to replace current paper forms or oversee their development and provide dates as to when these will be available.

   **Response:** Since the ATCSC meeting we have implemented web-based forms for two Facility Questionnaires (i.e. 3DCRT and IMRT) and also the digital data submission form (i.e. T2). We plan to have electronic forms for QA review by the end of the year. We will continue to emphasize the use web-based technology in our developmental and service efforts.

8. Dr. Purdy mentioned challenges for ATC including PET, stereotactic, gamma knife, etc. What are your plans for meeting these challenges? Where do they fit in your list of priorities?

   **Response:** Clearly these technologies are important and are being prioritized based on protocol development. RTOG 0236 (stereotactic) has come to the front regarding this list. New credentialing phantoms are being developed as well as a new localization-credentialing requirement. Efforts also continue in encouraging stereotactic TPS manufacturers to implement ATC compliant DICOM export capability. PET is integral to many COG protocols and is clearly being shown to be an important vehicle for developing treatment strategies. Images are currently being collected in hard copy and CD format by QARC based on the ability of institutions to forward the material. However, all of these items are lower priority than implementing ATC Method 1 at QARC and RPC.

9. Regarding the education mission of the ATC, there has been a huge effort to have meetings and teaching events, but it is unclear that these have drawn much attention. There has as yet not been a single case sent to the ATC from any group other than the RTOG. Thus the ATC is still little more than the former ITC. The ATC has not convinced the oncological community that they need the ATC. This is in part due to historical interactions with QARC but much of the fault lies on the lack of value that ATC has provided to QARC. The ATC must show the RCET, QARC, and RTC why it is of value for them. Success in that realm will ultimately be measured by manuscripts and grants written by individuals, institutions, cooperative groups, and manufacturers. This scientific interaction must be easily facilitated by the ATC and is probably the greatest challenge faced by Dr. Purdy.

   **Response:** We have worked very hard to integrate ATC technology into QARC, primarily focusing on ATC Method 2. Since the ATCSC meeting we have revised our strategy and are pursuing implementing ATC Method 1 at QARC by the end of 2004. We will continue to develop Method 2, but now at a lower priority. We also believe the effort the NCIC is pursuing to capture scanned and screen captured images (referred to as ATC Method 3) may have significant impact on the daily operation of the ATC QA centers, especially QARC..

10. Interaction with industry is very ad-hoc and it is unclear what the incentives are for industry to comply with the ATC. Creation of a DICOM standard will not completely solve this problem. Manufacturers have many propriety components to help them distinguish themselves. For example, Varian is said to be writing IMPAC unfriendly software. Efforts to coordinate with industry are critical or the industry problem will never be solved.

**Response**: We do not agree that our interaction is “very ad-hoc.” By far this effort has been our most focused and I believe our most successful. The ATC (originally, the RTOG 3DQA Center) has conducted a series of six technical workshops for treatment planning system manufacturers to assist and coordinate with them in the development of digital data exchange clinical trials. The first two workshops covered the implementation of the RTOG data exchange format, which was developed by the 3DQA Center. For the past four years, the workshop has addressed the consistent use of the DICOM RT objects to submit clinical trials data that are compliant with requirements of the ATC DICOM Conformance Statement.

During the 12 months from July 2003 to July 2004, four treatment planning systems (TPS) achieved ATC Compliant status. Dr. John Matthews of the ATC is currently in correspondence with representatives of several TPS manufacturers to assist them in testing and maintaining their DICOM export capabilities. In addition to the four ATC-compliant TPS, eight other systems are works-in-progress, and several of these are expected to achieve ATC-compliant status in 2004. Dr. Matthews provided assistance to manufacturers in interpreting the ATC DICOM Conformance Statement and in evaluating the ability of treatment planning systems to submit data to the ATC. Several manufacturers have expressed their appreciation for his assistance and for the use of the ITC Remote Review Tool, which allows manufacturers to visualize their treatment planning data as received and interpreted by the ATC and compare these views to those of their own TPS displays.

During the July 2003 to July 2004 interval, 40 institutions where credentialed using DICOM submissions, some for multiple protocols and some with multiple treatment planning systems. Additionally, during this time more than 194 DICOM data sets were submitted to the ITC, including 123 "dry run" cases, 50 protocol case data sets, and 21 phantom data sets (submitted for evaluation by RPC).

Dr. Bosch of the ATC has been involved in the development of the DICOM RT objects since their beginning in 1994. As part of the original Working Group on RT Objects (later named Working Group 7) he played a significant role in the original design of these information objects. As part of DICOM Working Group 18, he contributed to the design of the DICOM Clinical Trials Identification modules. The ATC continues to work through DICOM Working Group 7 in NEMA to maintain the specification of the DICOM RT objects.

In the past year, Dr. Bosch and the ATC have played a leading role in encouraging and demonstrating the implementation of DICOM export capabilities as part of the ATC/AAPM/NEMA DICOM Demonstration ("Connectathon") effort at the 2004 AAPM annual meeting. This continuing effort has served not only to make DICOM RT object export more visible in the medical physics community, but to strengthen relationships between the ATC and the engineering staff of TPS manufacturers responsible for DICOM development and testing.

11. Can the ATC resources be made available to ad-hoc cooperation among institutions outside the formal cooperative groups? Such cooperation is usually formed for defined projects and involves a small number of institutions.

    **Response:** We are currently working with JCOG in this manner. We have also proposed this to EORTC but have made little progress. We will continue to pursue this approach.

12. It is clear that ATC efforts for technological interchange between QA centers and participating institutions have two foci. First is the development of tools that allow the ATC-supported QA centers to access, review, and analyze information being stored at the ATC. This activity seems to be moving along well, and clearly the new tools provided by the ATC are well received by QARC, RTOG, and the RPC. It does appear, perhaps incorrectly, that the QA centers are more reactive to ATC efforts than proactive. I do not see evidence of QA center activity in the design of tools, more in suggesting refinements after tools have been initially released. More interaction up-front would seem to be more optimal. The second important interchange focus is between institutions and the ATC, in submission of protocols. For most institutions, this is really an interaction between different manufacturers of treatment planning and Record-&-Verify systems and the ATC. These efforts have not been as successful, and I don't see strong buy-in by most manufacturers to ATC goals. (They are participating, but the chain of events that instigates such development effort from manufacturers seems long.) Some suggestions to improve this would be to either (1) create a more formal method of interaction/communication between the ATC and the manufacturers, in hopes of jump-starting some of the development, or (2) finding ways of getting AAPM. ASTRO, and other groups to put more pressure on the manufacturers. AAPM is attempting this in the Connect-a-thon this year, but I think it needs to happen at higher levels than the members of WG-7.

    **Response:** ATC efforts so far have focused on developing the ability for institutions to transmit and the ATC members to receive and organize that data. Once this process is successful the QA centers will have "real" data to analyze and the requirements for the tools will be developed. Although interactions with the manufacturers are helpful, there will remain a need to be ready and capable to receive information in diverse formats. Over time, the goal of the ATC will be to influence these choices and perhaps limit them to a selected few for data transfer. Integration of the databases at various levels will insure uniformity of the dataset and make it compatible for outcomes research.

13. It seems to me that, although I support the "Method 2" goal of data submission, there is still a lot of hand paper / copying / data entry occurring at the QA centers that is slowing down data entry, as well as increasing the QA necessary at each node of manual entry. I wonder if the development of more Web-based forms entry would help this. With the combined effects of HIPAA, the security levels (in reality the lack thereof) of treatment planning systems, and the ever-increasing amount of data that will need to be submitted, I cannot see that on-line submission of data is a long-term prospect. While some effort is being placed on media-based data submission, I would think that more effort may be required here, with web-based forms used for base case information and other tools for review.

**Response:** Both ITC and RCET are emphasizing the use of web-based tools. The ITC Remote Review Tool is a prime example. We are also moving to web-based forms for the various Facility Questionnaires (e.g. 3DCRT and IMRT) and the digital data submission form (i.e. T2). We will continue to emphasize web-based technology in our developmental and service efforts.

14. My general impression is that the ATC is, in reality, a service group to QA activities of NCI/NIH funded protocols. As such, it would appear that their primary customers are the QA centers. This is somewhat an overlapping group, particularly for the ITC/ATC/RTOG linkage. I am pleased that QARC was so supportive of the ATC, since it would be easy for the ITC/RTOG history to push QARC to an unintentional secondary status. I do sense some loss of focus on the part of the ATC in serving its customers. This evidences itself in their activities at such meetings as AAPM and ICCR, where I am not sure that this focus ties in well. That said, it is clear that the ATC is moving towards a broader scope, much of which I support.

    **Response:** The RTOG and RPC continue to be the main users of ATC resources. That said, we are working hard to have QARC utilize these resources to support COG and PBTC protocols and we are making progress. We believe that QARC is a strong group that has a diverse data acquisition platform, which can be made stronger through its relationship with ATC.

15. I am impressed (and perhaps a bit discouraged) by the breadth of activity being undertaken by the ATC. The tasks that they have undertaken are formidable, and the fact that they are making progress on them says much to the dedication and efforts of the staff. That said, I worry that the breadth of activity may result in too many tasks being undertaken at one time, with a resultant elongation of timelines for major projects that would have more significant impact. I feel that there is some early evidence that this is occurring, though Jim is trying hard to keep things focused on the "big picture" goals.

    **Response:** The task list for this effort is formidable. However, we have little choice as we need to be working on several fronts at the same time to achieve the required objectives for the benefit of the clinical trials system. It must be understood that this grant is not developmental only but is supporting ongoing RTOG protocols. In the monthly conference calls (and at the regular full-day meetings held at the RTOG), the ATC members review pertinent protocol and developmental issues. Priorities are discussed and agreed upon with monthly dialogue. Developing a system for quality assurance for the partial breast irradiation trial is a top priority for the NCI therefore it is a top priority for the ATC. The interactions generated from this development will serve to further improve the scope of vision and the use of the electronic tools provided by ATC.