QA in Radiation Therapy: The RPC Perspective

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Abstract. The Radiological Physics Center (RPC) is charged with assuring the consistent delivery of radiation doses to patients on NCI-sponsored clinical trials. To accomplish this, the RPC conducts annual mailed audits of machine calibration, dosimetry audit visits to institutions, reviews of treatment records, and credentialing procedures requiring the irradiation of anthropomorphic phantoms. Through these measurements, the RPC has gained an understanding of the level of quality assurance practiced in this cohort of institutions, and a database of measurements of beam characteristics of a large number of treatment machines. The results of irradiations of phantoms have yielded insight into the delivery of advanced technology treatment procedures.

1. Introduction
The requirements of quality assurance (QA) were brought to the attention of the US public in 2000 when a report from the Institute of Medicine highlighted the frequency of patient deaths from medical errors. [1] While the magnitude of the problem was shocking – as many as 98,000 patients dying each year from such errors – practitioners of radiation therapy were probably better aware of both the problem and potential solutions than those of many other medical fields. QA has a lengthy and solid foundation in radiation therapy, resulting at least in part from its quantitative nature.

During the past few years, a number of significant radiation therapy errors have been reported. [2-4] Several reasons are postulated, including the introduction of, and increasing dependence upon, advanced technologies. [5-8] Several publications reported that the introduction of advanced technology equipment permitted errors to occur that might otherwise have been detected. [9] The demands of advanced technologies on department resources might have drawn resources from simpler or basic functions. [10]

2. The Components of a QA Program
Quality assurance (QA) is defined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as “All planned or systematic actions necessary to provide adequate confidence that a service or product will satisfy given requirements for quality.” [11] In radiation oncology, this means that a QA program must be (a) planned, meaning that it must be prospective; (b) systematic, meaning that it must be well organized and intended to address all appropriate aspects of performance; (c) and necessary, meaning that it should include only those activities that contribute meaningfully to maintaining quality. Ultimately, the QA program must provide “adequate
confidence” that the delivery of radiation therapy will meet published and reasonable expectations for quality, accuracy, and safety.

A critical aspect of a QA program is independence; that is, the QA procedures conducted to assure the quality and accuracy of the product or process (in this case the delivery of radiation therapy) must be independent of the product or process itself. The failure to establish independence can lead to the risk that the QA device merely mimics the performance of the parameter being measured, masking an error or change.

3. The Role of the Radiological Physics Center
The RPC was established in 1968 to contribute to the development, conduct, and QA of multi-institutional cooperative group clinical trials. A description of clinical trials and the role of several of the QA offices can be found in a report published by the AAPM. [12] The mission of the Radiological Physics Center is to assure NCI and the Cooperative Groups that institutions participating in clinical trials deliver prescribed radiation doses that are clinically comparable and consistent.

In 1999, the RPC joined with several other QA offices to form the Advanced Technologies Consortium. [13] The ATC currently consists of the RPC, the Image-Guided Therapy QA Center (ITC) in St. Louis, the Quality Assurance Resource Center (QARC) in Providence, RI and the headquarters dosimetry group of the Radiation Therapy Oncology Group (RTOG), located in Philadelphia. The role of the ATC is to support the development and conduct of advanced-technology clinical trials, and to facilitate communications among the four QA offices.

3.1. Remote Audits
The RPC initiated a program of mailed thermoluminescent dosimeters (TLDs) in 1977. [14, 15] The uncertainty of the TLD system to measure output of accelerators remotely has been evaluated and found to be 1.5%. [15] Consequently, the RPC’s measurement of an institution’s output can be stated at an uncertainty of less than 5% using a 99% confidence interval. When the TLD measurement disagrees with an institution’s stated dose by more than 5%, the RPC initiates a series of activities to resolve the discrepancy. If the discrepancy cannot be resolved through telephone calls and the review of procedures and documentation, an on-site dosimetry visit is scheduled. The RPC recently replaced the TLD system with one based on optically stimulated luminescence dosimetry (OSLD). [16]

3.2. On-site Dosimetry Review Visits
An on-site audit has been recommended by several organizations, including the AAPM and the IAEA. [17, 18] An independent audit is especially important for solo practitioners but is a valuable exercise for all practicing clinical medical physicists. It need not be extensive, but should address key activities such as basic calibrations, the overall QA program and documentation.

The RPC visit procedure consists of a review of the institution’s QA procedures and documentation; a review of treatment records to ascertain the consistency of the procedures used for treatment planning and monitor unit calculations; and measurements of the radiation beams and radioactive sources. The measurements include mechanical alignment and accuracy of position readout devices, light versus radiation field congruency, calibration of treatment machine output and brachytherapy source strength, relative field-size dependence, percent depth dose, off-axis ratio, some asymmetric jaw and irregular field parameters, and accessory transmission factors. Several measurements are designed to evaluate the basic data required for delivery of IMRT. Procedures for evaluating image-guided radiation therapy (IGRT) are under development, and procedures for visits to proton-beam facilities are currently being implemented.

3.3. Reviews of Patient Treatment Records
In some cases, the RPC (or another QA office) reviews the treatment plans prepared by participating institutions for patients registered on the clinical trial. When the number of patients to be registered is relatively small, and the protocol is complex, the study chair may require that institutions submit their
treatment plans for review before the patients are treated. The RPC often participates in such “rapid reviews” to ensure that the treatment plans meet the dosimetric requirements of the protocol. In other cases, the RPC performs retrospective reviews. The RPC relies on measurement made at the institution through the TLD program and on-site dosimetry reviews, or if a visit has not yet been made, its database of measured “standard” data. Using these data and the treatment parameters (field size, depth, MU setting, etc.) the RPC can independently calculate the dose received by the patient.

3.4. Credentialing for Advanced Technology Clinical Trials
Clinical trials that require the use of advanced technologies such as IMRT and prostate brachytherapy are considered sufficiently challenging that institutions are required to demonstrate their ability to use these technologies before being permitted to register patients. Credentialing for such clinical trials generally involves the completion of questionnaires, review of patients treated previously, computation and submission of a benchmark treatment plan, and in some cases, irradiation of an anthropomorphic phantom.

4. Results from RPC’s QA Audits

4.1. Annual Calibration Checks
Over the years, 5% to 6% of the US megavoltage beams audited with TLD have fallen outside of the RPC’s ±5% dose or 5 mm electron depth dose criteria on the first measurement. (Figure 1) With 3200 machines being monitored today, this represents approximately 700 beams. The RPC has determined that the approximately 750 institutions that have been visited have contributed about 85% of all clinical trial patients. Among these institutions, approximately 20% or 150 have one or more beams outside of the RPC’s criteria on an annual basis that require an investigation by the RPC. (Figure 2)

An annual independent audit coincides with the quality assurance standard requirement in most states that each beam be calibrated on an annual basis to ascertain that the output has not changed. The precedent for performing the TLD audit annually was established by the RPC many years ago and all current trial data and results are based on having this level of QA. A review of EORTC trial results indicated that decreases in tumor control probability were associated with discrepancies in the beam calibration, as measured by a TLD audit program. [19] At the same time, increases in normal tissue morbidity were associated with discrepant high TLD measurements. The article also indicated that sequential TLD audits improved the uniformity of the clinical outcome and that small deviations in beam output might lead to clinically important variations in outcome. Mailed TLD audits were deemed to be an integral part of quality assurance for trials.

Figure 1: The percent of megavoltage radiation beams at US institutions that fail to meet the RPC’s 5%/5 mm criteria for acceptability. The blue bars indicate the proportions at institutions visited by the RPC.

Figure 2: The percent of institutions irradiating TLD in any year that have at least one beam failing the RPC’s 5%/5 mm criteria for acceptability.
4.2. Measurements of Beam Parameters
Following a dosimetry review visit, the RPC generates a detailed report describing the observations and measurements that were made and the level of agreement with the institution’s planning data. The report clearly indicates any measurements that disagree by a significant amount with the institution’s data, and when the disagreements exceed appropriate thresholds, the report includes recommendations to the institution for improvement. These recommendations then demonstrate areas that require attention by the institution. When considered in aggregate, these recommendations form an indication of the areas of general concern at the visited institutions. The common recommendations and the frequency with which institutions receive them are shown in Table 1. Of note are the recommendations indicated by asterisks; these are considered important dosimetry parameters. Overall, 70% of visited institutions received one or more of these recommendations.

Table 1: Selected discrepancies detected during 2004-2008 during RPC dosimetry review visits to 165 institutions. The parameters indicated by asterisks are considered significant dosimetry parameters. During this 5-year period, 70% of the visited institutions received one or more recommendations to address discrepancies in these dosimetry parameters.

| Errors Regarding:                             | Number of Institutions (%) |
|------------------------------------------------|---------------------------|
| Review QA Program                             | 127 (84%)                 |
| *Wedge Transmission                           | 53 (32%)                  |
| *Photon FSD (small fields)                    | 46 (28%)                  |
| Off-axis Factors, Beam Symmetry                | 42 (25%)                  |
| *Photon depth dose                             | 34 (21%)                  |
| *Electron Calibration                          | 25 (15%)                  |
| *Photon Calibration                            | 22 (13%)                  |
| *Electron Depth Dose                           | 19 (12%)                  |

4.3. Reviews of QA Programs
The RPC judges the quality of an institution’s QA program against the AAPM’s TG-40 and TG-142 recommendations. [20, 21] A list of common failures or lapses in QA programs found by the RPC appears in Table 2.

Table 2. Common QA lapses and deficiencies found at institutions during RPC visits.

- QA records not available or maintained
- Annual calibrations or monthly checks not performed timely
- No record of comparison to clinical values on annual report
- No record of comparison of daily and monthly checks against annual “baseline” values
- Physicist review of daily checks not documented
- No record of corrective actions and repeat measurements
- Daily check of electron beam energy not performed
- Output or field flatness constancy with gantry angle not checked during annual calibration

4.4. Observations from Reviews of Patient Records
Over a 5-year period from 2005-2009 the RPC found systematic errors in 1% of charts, individual errors in 8% of charts, and transcription errors in 27% of the charts. In each case, the error was corrected by the RPC and reported to the study group so that correct information could be used for
evaluation of the clinical trial. The results of these reviews were also reported to the institutions promptly, to enable the institutions to take corrective action.

4.5. Results of Anthropomorphic Phantom Reviews

During the time period 2001 to 2009 the RPC mailed IMRT head-and-neck phantoms to 472 distinct institutions. See Table 3 and Figure 3. A total of 752 irradiations were analyzed. Of these, 585 irradiations or 78% successfully met the irradiation criteria. More than 350 institutions failed to meet the irradiation criteria on the first attempt and had to repeat the phantom irradiation. Of those failing to meet the accreditation criteria, the majority failed only the dose criterion. The remaining unsuccessful irradiations failed the distance-to-agreement (DTA) criterion or both the dose and DTA criteria.

Table 3. Passing rates for the RPC’s anthropomorphic phantoms. The criteria for agreement are 7 % and 4 mm for all phantoms except the lung phantom, for which the criteria are 5 % and 5 mm.

| Phantom | H&N | Prostate | Spine | Lung | Liver |
|---------|-----|----------|-------|------|-------|
| Irradiations | 752 | 174 | 19 | 174 | 23 |
| Pass | 585 | 143 | 13 | 124 | 12 |
| Pass % | 78% | 82% | 68% | 71% | 52% |
| Criteria | 7%/4mm | 7%/4mm | 5%/3mm | 5%/5mm | 7%/4mm |
| Year introduced | 2001 | 2004 | 2009 | 2004 | 2005 |

The average TLD/Institution ratio for the PTV structures was 0.99 with a standard deviation of 5%. The range of the measurements was large, with ratios extending from 0.44 to 1.26. The distance to agreement (DTA) for the high dose gradient region between the primary PTV and the OAR averaged 0.2 mm with a standard deviation of 3.1 mm. The majority of the phantoms met the 4 mm criterion. The range of the DTAs was from -15 mm to +17 mm. A negative DTA meant that an institution delivered dose posteriorly beyond the planned distribution and delivered a higher than intended dose to the OAR.

5. Summary and Conclusions

5.1. State of QA in the US

As described above, the majority of institutions audited by the RPC meet well-accepted criteria established by organizations such as the AAPM and RTOG. However, a significant number of institutions fail to meet these standards. The RPC’s mailed TLD program found reference calibration
discrepancies at 15% to 20% of the audited institutions each year of the last eight. During dosimetry audit visits, measurements with an ionization chamber in a water phantom were made of several significant dosimetry parameters. Seventy percent of the institutions visited had discrepancies in one or more of these parameters. In particular, the RPC disagreed with the institution’s calibration of one or more photon beams during audit visits to 13% of the institutions visited during the past 5 years. During reviews of treatment records, the RPC has disagreed with calculations performed by the audited institutions in 12% of the reviewed charts. Measurements of tumor dose delivered to anthropomorphic phantoms demonstrated that institutions delivered the intended tumor dose within the 7% / 4 mm DTA criteria 75% to 80% of the time.

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