Published in final edited form as:

Health Phys. 2014 January ; 106(1): 97–105. doi:10.1097/HP.0b013e3182a2a987.

The MCART Radiation Physics Core: The Quest for Radiation Dosimetry Standardization

Abdul M. Kazi*, Thomas J. MacVittie*, Giovanni Lasio*, Wei Lu*, and Karl L. Prado*

*University of Maryland, School of Medicine, Department of Radiation Oncology, Baltimore, MD

Abstract

Dose-related radiobiological research results can only be meaningfully compared when radiation dosimetry is standardized. To this purpose, the National Institute of Allergy and Infectious Diseases (NIAID)-sponsored Medical Countermeasures Against Radiological Threats (MCART) consortium recently created a Radiation Physics Core (RPC) as an entity to assume responsibility of standardizing radiation dosimetry practices among its member laboratories. The animal research activities in these laboratories utilize a variety of ionizing photon beams from several irradiators such as 250–320 kVp x-ray generators, ^{137}Cs irradiators, ^{60}Co teletherapy machines, and medical linear accelerators (LINACs). In addition to this variety of sources, these centers utilize a range of irradiation techniques and make use of different dose calculation schemes to conduct their experiments. An extremely important objective in these research activities is to obtain a Dose Response Relationship (DRR) appropriate to their respective organ-specific models of acute and delayed radiation effects. A clear and unambiguous definition of the DRR is essential for the development of medical countermeasures. It is imperative that these DRRs are transparent between centers. The MCART RPC has initiated the establishment of standard dosimetry practices among member centers and is introducing a Remote Dosimetry Monitoring Service (RDMS) to ascertain ongoing quality assurance. In this paper we will describe the initial activities of the MCART RPC toward implementing these standardization goals. It is appropriate to report a summary of initial activities with the intent of reporting the full implementation at a later date.

Keywords

dosimetry; calibration; quality assurance; radiation dose; radiobiology; standards; x-ray machines

INTRODUCTION

The MCART Consortium's objective is to pursue the strategic plan of the National Institute of Health (NIH) to conduct research on developing medical countermeasures (MCM) against radiological and nuclear threats. One of the highlighted goals of this basic and translational research (NIH Strategic Plan and Research Agenda. 2005) is to find mechanisms of radiation injury and therapy at the systemic, organ, cell, and molecular levels, and to identify and verify potential targets for MCM against radiation injury. The strategic plan also highlights use of new animal models to test and evaluate promising countermeasures. The development of MCM against the acute radiation syndromes requires well characterized and validated animal models (MacVittie 2012a). These models must

For correspondence please contact: Abdul M. Kazi, Department of Radiation Oncology, University of Maryland School of Medicine, 10 S. Pine St., MSTF, 6-00, Baltimore, MD 21201, Phone: 410-706-3865, Fax: 410-706-5270. or akazi@som.umaryland.edu.

Conflicts of interest

The authors declare no conflict of interest.

experimentally verify radiation dose- and time-dependent relationships for mortality and major signs of morbidity for the hematopoietic (H) and gastrointestinal (GI) sequelae of the acute radiation syndrome (ARS) and lung injury of the delayed effects of acute radiation exposure (DEARE).

The required accuracy of dose specification in these experiments is very significant due to the fact that the DRR curve is very steep. To appreciate the steepness of DRR we show two examples. In Figure 1a below, it can be seen that a variance of $\pm 10\%$ in dose can lead to an indeterminacy of mortality of rhesus macaques between 12%–80%. In Figure 1b (Plett et al. 2012a), it is clear that the gradient is even greater where a 10% variance could result in a mortality range of 5%–90% in the case of mice models (MacVittie et al. 2012b).

Because of the sensitivity of dose response to dose it is incumbent upon researchers in this field to pay extra attention to dose measurement procedures. The measurement of dose has its own inherent uncertainties. By themselves and even under reference conditions, basic calibration measurements contribute uncertainties in the order of $\sim \pm 2$ to 5% (Kutcher et al. 1994, Almond et al. 1999, Ma et al. 2001). As irradiation conditions depart from these reference circumstances, additional uncertainties are introduced.

Uncertainties in dose specification strongly depend not only upon the type and energy of the irradiators, but also the accuracy and thoroughness of the irradiator characterization measurements and hence the level of radiation physics support that is provided. Uncertainties built into the dose determination process can never be avoided completely, but with careful development and subsequent adherence to well-designed standard policies and procedures, one can help minimize them to an acceptable level. With the understanding that a common standard of dose specification throughout consortium laboratories will improve transparency of research results, the MCART decided to form a Radiation Physics Core (RPC).

As stated earlier, the principal goal of the MCART RPC is to achieve dosimetry standardization among MCART consortium research sites. When dosimetry standardization is in place, one of the two key variables that affect the radiobiological response becomes relatively independent of the laboratory. Accurate and consistent delivery of the prescribed radiation dose(s) aids in controlling the additional physical and biological variables that can significantly affect the biological response. These include individual animal radiation sensitivity, variable loss of body weight, anorexia, and dehydration as key markers of morbidity, differential duration of neutropenia and thrombocytopenia leading to requisite antibiotic administration and transfusions, daily use of ketamine for large animals, handling of small animals for injections via subcutaneous, intramuscular or oral routes as noted in recent publications describing the MCART animal models (MacVittie et al. 2012b, MacVittie et al. 2012a, Booth et al. 2012a, Booth et al. 2012b, Farese et al. 2012, Plett et al. 2012, MacVittie 2012a, Jackson et al. 2012). It would have been reasonably straightforward to establish such dose specification transparency if all the Consortium labs were using same radiation type, and same setup and dose calculation protocols, but unfortunately these sites differ in all three accounts. Thus a major role of MCART RPC is focused on resolving dose specification differences.

To this goal, we followed an established model - The Radiologic Physics Center at MD Anderson Cancer Center (MDACC RPC) was funded by National Cancer Institute (NCI) in 1968 to provide quality auditing of dosimetry practices at institutions participating in cooperative clinical trials. The mission of the MDACC RPC is stated in their website (MDACC RPC 2013):-

“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. We do this by assessing the institutions radiotherapy programs, helping the institutions implement remedial actions, assisting the study groups in developing protocols and QA procedures, and informing the community of our findings.”

It is instructive to look into excerpts from the history of the MDACC RPC which can also be found in their website (Radiological Physics center 2013),

“The primary responsibility of the RPC is to assure the NCI and the cooperative clinical trial groups that all participating institutions have the equipment, personnel, and procedures necessary to administer radiation doses that are clinically comparable and consistent. The monitoring tools include on-site dosimetry reviews; remote auditing tools, including thermoluminescent detectors (TLD) and review of both anthropomorphic phantoms; and reviews of benchmark and actual protocol patient treatments.”

It should be emphasized that the level of success in standardization achieved by MDACC RPC was largely dependent upon requiring participating clinics to: 1) use dosimetry instruments calibrated from an Accredited Dosimetry Calibration Laboratory (ADCL) traceable to NIST, and 2) follow a single national protocol for dose calculation such as AAPM Task Group 51 (TG-51) (Almond et al. 1999). In addition to providing remote dosimetry auditing, the MDACC RPC also serves as a useful resource center for clinical medical physicists to obtain guidance when participating in national clinical protocols.

Given the similarity in goals, the MCART RPC will follow the path established by MDACC RPC. The details of the initial development of such an endeavor are described in the remainder of this paper.

MATERIALS AND METHODS

Organization and Personnel

The MCART RPC will serve as the radiation dosimetry liaison for the MCART Consortium. At present there are five centers participating in MCART animal radiobiological research:-

1. Pre-Clinical Radiobiology Lab (PRL), University of Maryland, School of Medicine, Baltimore, MD
2. Division of Translational Radiation Sciences (DTRS), University of Maryland, School of Medicine, Baltimore, MD.
3. Indiana University, School of Medicine (IU), Indianapolis, IN
4. CiToxLab North America, Laval, Quebec, CA
5. Epistem Ltd, Manchester, UK

One of the goals of the MCART RPC is to establish a mechanism to communicate potential changes and updates in dosimetry in a transparent manner between the centers. To facilitate this goal, the RPC's organizational structure is extended into each participating lab. At each facility a physicist-liaison is identified who is involved in the local MCART research activities. The identification and active involvement of physicist liaisons is seen as critical to the success of the standardization effort. A proposed organizational chart is shown in Fig. 2:

Equipment, Database development and implementation of RDMS

The MCART RPC's primary dosimetry system will include a farmer type ion chamber and precision electrometer for measurement of absolute dose in a reference setup following an appropriate national protocol. The ion chamber and the electrometer both will have valid ADCL calibration factors. The MCART RPC will also acquire an additional small volume ion chamber to facilitate measurements for small field geometry needed for partial-body irradiation situations. For this small field ion chamber MCART RPC will establish traceability to NIST by inter-comparison with its primary dosimetry system. Similar reference instrumentation will be needed at each site.

Following the MDACC RPC, the MCART RPC will use Optically Stimulated Luminiscent Dosimeters (OSLD) for remote monitoring purposes. The MCART RPC will use screened nanoDots and Landauer microStar InLight Reader to develop this database. The screened nanoDots are chosen because it has a better accuracy rating ($\pm 5\%$) compared to non-screened nanoDots. The data set will be comprised of:

- Site-specific microStar calibration data: Readings from a set of nanoDots irradiated to a set of known doses using a reference calibration protocol setup to determine a site-specific calibration configuration in the RPC's microStar Reader.
- Baseline data for mouse phantom irradiation: Readings from a set of mouse phantoms embedded with screened nanoDots in standard setup geometry to establish an initial database. This database will be used in future to evaluate dosimetry status of a site when a nanoDot embedded mouse phantom is returned to RPC after being irradiated at a site following specific instructions provided by RPC.

The setup will involve a plastic platform with supporting legs to ensure specified distance of the mouse phantom from a therapy couch or from a metal base in an x-ray irradiator. Two types of mouse phantoms will be used to develop the database for output check as well as monitoring energy characteristics of the site beam. One with the capacity of holding three nanoDots in place along the long axis (Figure 3a) and the other will have the capacity of holding six nanoDots in three rows of two (Figure 3b) of which the first row of two nanoDots will be shielded by a 1-mm Cu screen. The ratio of signals between nanoDots with Cu screen to those without Cu screen will characterize the energy of the irradiator.

The MCART-RPC will develop a centralized dosimetry database by collecting actual measured data for standard reference setups from each center. These dosimetry data will be comprised of two types, a) that used to calculate dose to irradiated animals and b) that used for remote monitoring purposes. The dosimetry data used for dose specification will consist of the following determinations:

- Output of the irradiator following AAPM dose calibration protocols such as TG-51 (Almond et al. 1999) for Linacs and TG-61 (Ma et al. 2001) for x-ray irradiators using an ADCL calibrated dosimetry system
- Ratio of the normalized (corrected for temperature and pressure) response from an Ion Chamber placed in a daily QA setup for a specific time of irradiation to the previously recorded normalized response at the protocol reference point irradiated for the same amount of time in calibration setup to assess output when a daily output check is performed.
- Ratio of dose to each animal at irradiation positions to the dose at protocol reference point

- Field size effects on the output at irradiation positions if multiple field sizes are used for example in partial body irradiations.
- Effects of distance and shielding on animal irradiations
- Uniformity of the beam used for animal irradiation at the level of animal irradiation positions.

The above data acquired for each center will serve as baseline data for future quality assessment purposes.

Once the initial database is developed then remote monitoring can be accomplished as follows:

- On a periodic basis a mouse phantom irradiation package will be shipped to each site. The package will contain two mouse phantoms per irradiator. One will be Type 1 with 3 nanoDots and the other will be of Type 2 with 6 nanoDots with 2 of them under a Cu screen. The package will also contain a plastic irradiation platform and specific irradiation instruction designed for this purpose.
- After receiving the package the liaison physicist will irradiate the mouse phantoms according to RPC provided instruction and ship the package back to RPC.
- The RPC physics staff will read the irradiated nanoDots and evaluate the quality of the site beam by comparing measured dose to expected dose from site specific baseline data.

Initial Experience: Commissioning of a 320kVp cabinet x-ray machine system for the MCART, Division of Transitional Radiation Science (DTRS)

For absolute dose measurements under reference conditions we used a PTW 30001 ion chamber and Kiethley 35024 electrometer with valid ADCL calibrations and followed the AAPM TG-61 protocol recommended in-air calibration formalism to establish a dose rate at the center of 10 cm × 10 cm field at a distance of 50 cm from the source. To determine dose relationships relevant to animal-irradiation geometries we made relative measurements using an ion chamber with a calibration factor established via inter-comparison with the ADCL calibrated chamber. In addition we used following accessories to complete the tasks:-

- GafChromic EBT2 and RTQA film and a EPSON flatbed scanner
- Polystyrene mouse phantoms with receptacles for PTW 0.6 cc Farmer chamber and for IBA CC04 chamber (Figure 3c)
- Mouse irradiation jig (Lucite)
- 0.8 cm thick rectangular lead add-on shields for the mouse irradiation jig (these shields are used to limit the irradiation field to only the lungs)
- Support stand for the ionization chamber with clamp for in-air measurements

Some of the measurements are mentioned here briefly to highlight the physics activities at this specific research site:-

- Measurement of Beam Quality (Half Value Layer measurements).
- Calibration of in-air dose rate according to the AAPM TG61 protocol
- Calibration of in-phantom dose rate at the animal irradiation point using a small volume ion chamber inserted in a mouse phantom.

- Dose uniformity at the animal irradiation positions, and subsequent assignment of an average dose rate; statement of beam uniformity throughout the irradiation field.
- Output factors for shielded geometry-dose rate as a function of shield gap:
- Determination of dose linearity across all possible mice - exposure protocols.

RESULTS

We performed Acceptance Testing, Commissioning, Output Calibration, and Irradiation Geometry Dose Specification on a newly acquired XRAD320 cabinet x-ray system prior to its release for animal irradiation. This unit is used to irradiate the lungs (only) of mice in a protocol named Whole Thorax Lung Irradiation (WTLI).

The above figures (4a and 4b) show example of beam quality measurements and dose linearity measurements for XRAD320 using technique 320 KV, 12 mA and F1 Filter (2mmAl). Details of these measurements as well as other XRAD320 commissioning related data can be found in the unit's December 2012 commissioning report (Lasio et al. 2012).

In addition to the above mentioned activities, we developed Standard Operating Procedures (SOP) for the following specific objectives:-

- Routine output checks for on-going quality assurance of the irradiator (a sample of output QA form shown in Figure 5).
- Animal irradiation protocols to ensure quality management (a sample dose-prescription form and a beams-eye-view of the lung-irradiation geometry are shown in Figure 6 and Figure 7 respectively).
- A protocol for intra-irradiation port film to evaluate quality of irradiation geometry (a sample port film is shown in Figure 8).

These are fairly intensive and focused physics activities. The last two items required a multi-disciplinary collaborative effort between physics and other research staff involved in the procedure. As an example of the improvements in accuracy that can be achieved with appropriate physics support, figure 8 reveals that an intra-irradiation port film can provide an insightful opportunity for the investigators to either eliminate some mice from the study or take into account of the fact that a subset of the mice population either did not have 100% of their lung irradiated, or had significant inclusion of GI anatomy.

DISCUSSION

The need for dosimetry accuracy and precision in MCART's radiobiological research is underscored by the challenges of DRRs that are commonly encountered. A very sensitive relationship exists between biological outcome – the y-axis of the DRR – and delivered dose – the x-axis of the DRR. Meaningful biological conclusions can only be drawn from statistically-distinct dose-response data. This requirement places enormous accuracy and precision demands on the determination of dose. Without exact radiation dosimetry, the DRR cannot be properly established and consistent in predicting the dose delivered and the consequent biology. The success or failure of dose-effect-modification strategies is routinely determined from changes observed in animal survival at the 20% to 80% or 90% survival levels. If an experiment warrants statistically valid survival differentiation in this range, then dosimetry precision at the level of $\pm 5\%$ will be needed. This precision is rarely achievable without a rather significant uncertainty reduction effort. Uncertainties compound at every step along the way – from calibrations of measurement equipment and irradiators, to delivery of radiation to experimental subjects. Only through carefully designed and

rigorously implemented QA measures can uncertainties be minimized on the x-axis to the degree that is necessary/required for meaningful and consistent biology on the y-axis.

The MCART RPC was formed to accomplish this required reduction in radiation dosimetry uncertainty. Among its principal goals are standardization of radiation dose measurement and delivery, and continued preservation of this standardized dosimetry system. The MDACC RPC has very successfully accomplished these goals at medical institutions participating in clinical trials. We strongly believe that a similar system should exist for animal experimentation, and we are adopting a system that is modeled from the MDACC RPC. Their system of periodic on-site dosimetry measurements, remote dosimetry monitoring, reviews of quality assurance procedures, and radiation physics consultation, has served the clinical-trial community very well. Similar results are expected from the MCART RPC.

We have pointed out that dose uncertainty can easily exceed our required precision unless rigorous control is exerted on quality assurance of equipment and procedures, but this presupposes that the parameters measured by the equipment and controlled by the operating procedures have been already identified as the ones that most completely determine the dosimetric results of a specific study. In reality, there is currently no clearly defined guideline on what irradiation parameters - for example: dose to water/air, reference dose determination, dose rate, irradiation geometry, beam quality, measurement equipment characteristics, irradiator type, radiation source characteristics, irradiation subject characteristics, etc. - should be tracked as the minimal significant set, for the purpose of radiobiological dose inter-comparison. The MCART RPC will be in the unique position of being able to define this set of most relevant parameters, collecting measurements across several institutions and providing written reference standards that will be used for guidance in the radiation biology community.

The very first step toward achieving dosimetry standardization, compilation of site specific information, is underway. A comprehensive Facility Questionnaire has been sent to all centers and they were being completed and returned to the RPC. Information requested in the questionnaire includes staff, facility, and equipment data. This baseline information will help facilitate a subsequent site visit by the RPC to each site. During the site visit, additional measurements will be made of each irradiator that is used for MCART research. These measurements will help link the specification of dosimetry at each site.

The MCART RPC had its first meeting in November, 2012. In attendance were all physicists that are currently involved in MCART activities. Goals were presented and challenges were discussed. The current structure of physics support at all centers is not conducive to expecting full-fledged attention of a local physicist in this standardization endeavor. The physicists involved in the MCART consortium centers are normally medical physicists in clinical practice who provide additional services in support of animal research activities. Given the additional work needed to develop and maintain meaningful dosimetry standardization, it is imperative that each site designate and properly fund a clearly-tasked liaison physicist for the required activities of the MCART RPC.

CONCLUSIONS

From the activities and developments described above we continue to develop the RPC and fulfill our objectives for standardization of dosimetry among MCART consortium laboratories. We are proceeding with a clear goal and mission to minimize the uncertainty of dose specifications in these centers. Undoubtedly the task at hand is significant because of the diversity between respective dosimetry systems but a consistent effort will pave the way

to our goal. The predictive ability of our animal models is absolutely dependent on our ability to deliver the proscribed dose to the target tissue.

Acknowledgments

This work has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN277201000046C.

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Figure 1.

Figure 1a. Percent Mortality vs. Dose of TBI in rhesus macaques.
Figure 1b. Radiation dose response relationship of C57BL/6 mice

Figure 2. MCART RPC organizational chart. The abbreviations used are as follows: - UMB: University of Maryland, Baltimore, RPC: Radiation Physics Core, H: Hematopoietic, GI: GastroIntestinal, ARS: Acute Radiation Syndrome, DEARE: Delayed effects of Acute Radiation Exposure.

Figure 3.

Figure 3a. Mouse Phantom with holding capacity of 3 nanoDots with one dot mark on top.

Figure 3b. Mouse Phantom with holding Capacity of 6 nanoDots with two dot marks on Top.

Figure 3c. Mouse phantoms with ion chamber receptacles.

Figure 4.
Figure 4a. Beam Quality measurement
Figure 4b. Dose Linearity measurement

PRE-IRRADIATION DOSIMETRY LOG for XRAD320 (at DTRS)

Date: _____ Bias Check Trigger: If Electrometer Voltage is less than 297, please change batteries

Prior to each irradiation please Verify:

1) Ruler on back wall of the irradiation cabinet indicates the Metal Plate is at 73 cm
 2) Irradiation jig and Ion chamber are aligned with machine cross-hair
 3) Technique set at KV: 320, mA: 12, Filter: 1 2mmAl, and duration: 60 s

Equipments: Ion Chamber (choose one) 1) PTW Farmer SN 0412, 2) PTW Farmer SN 1147
 Electrometer CNMC 206 SN 1193012
 Thermometer
 Barometer

Performed By (Initial)	TEMP. (°C)	PRESSURE (mmHg)	Ptp (from Table)	Reading 1 (nC)	Reading 2 (nC)	Average Reading (nC)	Corrected Average (nC)	Expected Reading (nC)	COMMENTS
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	
								34.1	

ACTION TRIGGERS:

1. IF 33.1<CORRECTED AVERAGE<35.1; ==> NO ACTION NECESSARY
2. IF CRITERION 1 failed but 32.4<CORRECTED AVERAGE<35.8; ==> CALL PHYSICIST
3. IF CRITERION 2 failed; ==> CALL STUDY LEADER, PHYSICIST and SERVICE

Approved by: Abdul Kazi, Ph.D. 1-18-2013

Figure 5.
Pre-Irradiation Dosimetry Log, to record output QA to be performed prior to each irradiation.

Determination of Total Exposure Time for Research Animal Irradiation

Machine: XRAD320, Precision X-Ray, Inc.
640 Howard Hall, University of Maryland
Irradiation Technique: 320 Kv, 12 mA, Filter F1 (2mmAl)

Study Protocol #:		IACUC #:	
Cage Card# of Mice to be Irradiated:			
Prescribed average dose to Irradiated Positions:			Gy
Prescribed Shield Gap width to be used for irradiation:			cm

Prescription Approved By: _____; Date: _____

Average dose rate to IP for open field (from Annual Calibration):	1.56	Gy/min
Shield Gap factor for the prescribed gap (from Table):		%
Average dose rate for this prescription:		Gy/min

Total Time (sec) = 60 * Dose (Gy) / (Average Dose Rate (Gy/min))

T = _____ seconds

Total time calculated By: _____; Date: _____

Date of Irradiation:	_____
Pre-Irradiation Output verified at:	_____
Pre-Irradiation Setup verified at:	_____
Irradiation Started at:	_____
Irradiation Stopped at:	_____

Table of Shield Gap Factor

Shield Gap (cm)	1	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2
Shield Gap Factor (%)	78.2	78.9	79.7	80.4	81.2	81.9	82.3	82.7	83.1	83.5	83.9

The numbers in bold are from Annual Calibration and numbers in italics are interpolated.

Figure 6.
A sample prescription form to be filled out prior to animal irradiation.

Figure 7.
Removable Pb shields used for lung irradiation. Pb sheets A and E are 8 cm wide; B, C, and D are each 4 cm wide. The width of the gap is changed by moving section E and A.

Figure 8.

A sample of intra-irradiation port film clearly showing extent of lung being irradiated. The occurrences of less than 100% lung irradiations are indicated by 'X' marks.