

Credentialing Requirements for NSABP B-39 / RTOG 0413

Jessica R. Lowenstein, Joye Roll, Cynthia Davis, Paul Holguin, Huy Duong, David S. Followill, and Geoffrey S. Ibbott

Department of Radiation Physics

The University of Texas, M.D. Anderson Cancer Center, Houston, Texas



Purpose:

NSABP B-39 / RTOG 0413 is a Phase III trial comparing Whole Breast Irradiation versus Partial Breast Irradiation (PBI). The partial breast arm consists of 3 techniques, 3D Conformal Radiation Therapy, MammoSite and Multi-catheter HDR. For each of these techniques NSABP and RTOG requires an institution, radiation oncologist and physicist "team" to be credentialed. Credentialing requires completing knowledge assessment and facility questionnaires, importing a DICOM CT image set, performing a treatment plan using the image set and exporting the images, structures and isodoses to the Image-Guided Therapy QA Center (ITC).

Methods and Materials:

An institution can obtain the knowledge assessment and facility from RPC's questionnaires the website (http://rpc.mdanderson.org). These questionnaires can be completed online, emailed, faxed or mailed directly to the RPC. An institution may be credentialed for one or more of the PBI techniques. A CT benchmark case exists for each PBI technique. The institution is required to import the appropriate CT image set into their treatment planning system. The benchmark must be planned per protocol. The benchmark must then be digitally exported to the ITC along with all required hard copy data. The RPC will review each benchmark case submitted. Once the RPC has completed its review NSABP will be informed that the institution has met the requirements for credentialing and will be allowed to enter patients on the protocol.

PBI Credentialing Requirements:

Each Radiation Oncologist and Physicist team must complete the credentialing process before a patient can be placed on the protocol (See Section 5.1 of the protocol). Once the team has met the minimum requirements for credentialing, a letter will be sent to the Radiation Oncologist from NSABP informing them that they have successfully completed the credentialing process and can begin placing patients on the study.

Each Radiation Oncologist and Physicist team at an institution must complete the PBI QA Knowledge Assessment and Facility Questionnaires and complete the benchmark case for each PBI technique for which the institution wants to be credentialed. (Note: If a Radiation Oncologist at the same institution has been credentialed previously, then all subsequent Radiation Oncologists need ONLY to complete the PBI QA Knowledge Assessment Questionnaire and Sections I and II of the PBI Facility Questionnaire.)

Questionnaires:

PBI QA Knowledge Assessment Questionnaire (complete

- online or mail/email Microsoft Word document)
- PBI Facility Questionnaire (complete online or mail/email
- Microsoft Word document) Benchmark Cases: For each PBI technique (3D CRT,

MammoSite or Multi-Catheter) for which an institution would like to be credentialed, the specific benchmark case must be planned per protocol and submitted electronically to the ITC (see below on How to Submit Digital Data). A completed PBI treatment dosimetry summary form (either 3D CRT or MammoSite/Multi-Catheter) must be completed and a hard copy of the plan, including isodose lines and BEVs, must also be mailed to the RPC at: 7515 S Main Street, Suite 300, Houston, TX 77030

Click on one of the treatment planning systems listed below to download the proper CT image set. Some of these image files have been compressed (i.e. zipped) and must be decompressed using decompression software such as winzip. If the files cannot be downloaded, it's highly probable that your institution's firewall is preventing the transfer. This can be resolved by calling your IT department or downloading the images from outside the institution's firewall such as your home pc.

- Philips Pinnacle 0 CMS XiO
- 0 Nucletron Plato
- All other treatment planning systems 0

Methods and Materials continued:

How to Submit Digital Data(click on links to download procedures).

Digital data for PBI credentialing (benchmark cases) as well as ALL PBI protocol cases are to be submitted to the Imageguided Therapy QA Center (ITC) using either DICOM or RTOG Data Exchange format. The ITC will process these data and make them available for review by study chairs (or designates). the RPC, and the RTOG HQ Dosimetry Group. For further information and to obtain an FTP account for submitting data, please contact the ITC (314-747-5415 or itc@castor.wustl.edu).

Checklist for Digital Data Submission to the ITC Digital Data Submission Procedures Digital Data Submission Information Form ATC Compliant Treatment Planning Systems

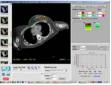




Methods and Materials continued:

NEARPHITICS FROM TROOM IN THE PROTOCOL FACILITY CALENTIALIZED	
	C. Statement Reporting to 19 Patron New Page
Passe 30 out at that apples is your institution. This will help separate the predectedness areases it	100m
	tw
L. Radiation Decology Facility:	 Sectionary Reports to 19 Pages
Address	her
One is a server to be in the factory of the factory	
Owah He appropriate and proceeds finality's transfer surface. [D1014	A former
	R. (Frammer and junctor and model) R. (Frammer junctor and model)
8. PERSONAL CONTACT INFORMATION	R. (7 scarce (web) and robb)
A Relation Drounger Responden for Hit Teacher	6. Hill all parts period
Non Para	 Pressure of 101 source spicement
Annua /w	
	Ri-Conferent Tente and anter
1. Procee Texpension for 192 hadress	New and The CP images and each the place range 1 (200) (Department Dilighteen from framinans (Departmentally in reduced)
ken hen	
	The are (TV - T) and some lines control advant (1) When a parenty unles (1) advance (1) are into (1) advance (1) are into
Ind	Contract or premining system Contract or CT and the Other instantic
	(Mar (separa) (Mar (separa) Mark Mark Mark (separation in mark
	intervention in theme and the state of the sectory
	Dear reform Variagemen analysis at Disayon (Plasma 1944 in dres in anti, the annual) of the tradition plasma
BY dis report and top to change has to RY (dip for relations rep	
The second	10 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
New York Country Country on April 21	ParticiProse Institute Facility Scientific rules
Results & Relation Residence	V. Palant April A: Grafty Description Providence
Tender and annum Ten are the (17 magin interest to planning?	 Inserting the most presented follower's ansars that the base on the regularization of the postcol. Insertion entropy, an approximate a contribution and their positions that are the positions of the california continued indexes further.
	The are the positions of the safetime continued belows factors
One (septer) Here are CPL PT1 and none linear united arises?	-
Cheffeet or utering suters Cheffeet or CT and tool as done	Fine are progin on the Mannuths technique, industrialistic program in the
	a Contentione of the lates in the latter of the Con-
(has obre tempere adueted to organ? Dre De	In Distance from Section auffect in the still auffect (2) and
Dear others hangens and dear an pagina? One One	n The tensors density of the tables
Noted a standard party for the standards that is to 350 parts is sub-obset from other thanges and part and part here the dense to be provided to a standard to a standard to a the provided to a standard to a standard to a standard to a the provided to a standard to a standard to a standard to a the provided to a standard to a standard to a standard to a the provided to a standard to a standard to a standard to a the provided to a standard to a standard to a standard to a standard to a the provided to a standard to a standard to a standard to a standard to a the provided to a standard to a standard to a standard to a standard to a the provided to a standard to a the provided to a standard to a standard to a standard to a standard to a standard to a standard to a standard to a standard to a standard to a the provided to a standard to a standard to a standard to a standard to a standard to a standard to a standard to a standard to a sta	
Placent d'unité la la la seu voir ann man palei latrique	 Epimetry of sector larger of the balance within the crisise last
Ryte Ohigen Ofelster Destiger	A Posterial Advance of Tacadam Char. Char
K. HOR Stachylanapy Guelly Insurance Procedures	····
 A device already serilution fadritis description of the providence followed to well, the selected of the excession 	Vit Data Bulantantan Matariak may be decimitariya anti ito gan@extendence.org
 Receptor of Advanced custom. 	MAAPERTOL PER Contentiating on Cystella-David Restrictions of Physics Content THE 1. Basic Street, Name 201 Research, 93 THE
 Measurement and calculate techniques, including convenient of the above elevated into the examine specification units and factory freedown princing computer. 	7910 B. Balo Divert, Balle 200
 Transform of cardinals Stocks without 	
8. Source postering in the satisfier	
 Description party answers (b) providers and to only hat saves particle with the solution and input statements). 	
G. Enalmetry procedures	
 What is done to servic the accuracy of the insulment standing system? Natural accuracy monthly and easy (or checks to (10)) Description and the control of accuracy of the insulment is data standing. 	
 Describe any other Shipmanone permanents along signations. 	
	1





Multi-catheter benchmark

Results:

As of mid-July, 151 Radiation Oncologists have been credentialed to participate on the PBI arm of this study using the 3D conformal therapy technique, 71 have been credentialed to use the MammoSite technique and 31 have been credentialed to use the multi-catheter technique. The RPC has had 160 institutions apply to be credentialed using 3D conformal therapy of which 77 are credentialed. The RPC has had 104 institutions apply to be credentialed using MammoSite of which 53 are credentialed. The RPC has had 33 institutions apply to be credentialed using Multi-catheter of which 13 are credentialed.

The RPC starts the credentialing process for this study once we have received the knowledge assessment, facility questionnaire and a hard copy of the benchmark case. The RPC considers this a "complete RPC package." If one of these items are missing the RPC will contact the institution and request the data which is missing. Credentialing can not be completed until the benchmark case is electronically sent to the ITC. The following table shows the average amount of time it takes an institution to complete the credentialing process once they have submitted "complete RPC package.

	Average time to be <u>credentialed</u> (days)	Minimum time to be <u>credentialed</u> (days)	Maximum time to be <u>credentialed</u> (days)
3D	23	1	119
MammoSite	29	1	96
Multi-Catheter	30	1	85

Conclusions:

The purpose of credentialing is to verify that the radiation oncologist and other personnel involved are familiar with the protocol and can plan a case per protocol prior to placing a patient on protocol. This process enables us to give a "team" feedback prior to treating a patient on the trial potentially enabling us to reduce the number of deviation incurred on the trial

Support:

The investigation was supported by PHS grants CA10953 and CA81647 awarded by the NCI, DHHS,



3D conformal benchmark

MammoSite benchmark