

# SBRT Credentialing: Understanding the Process from Inquiry to Approval

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IROC Houston QA Center

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# What is credentialing?

- Verification of an appropriate level of competency, typically as a snapshot in time
- Can apply to all of specific combinations of institutions, radiation oncologists, physicists, TPS or treatment modality.

# Purpose of Credentialing

- Educate, educate, educate
- Improve understanding of protocol
- Evaluate ability to deliver dose
- Improve treatment delivery (contouring, IGRT, etc.)

**Goal is to reduce deviation rates**

RT Credentialing Requirements	Web Link for Procedures and Instructions: <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a>			
	Treatment Modality			Key Information
	SBRT	IMRT	Proton	
Facility Questionnaire	X	X	X	The IROC Houston electronic facility questionnaire (FQ) should be completed or updated with the most recent information about your institution. To access this FQ, email <a href="mailto:irochouston@mdanderson.org">irochouston@mdanderson.org</a> to receive your FQ link.
Credentialing Status Inquiry Form	X	X	X	To determine whether your institution needs to complete any further credentialing requirements, please complete the "Credentialing Status Inquiry Form" found under credentialing on the IROC Houston QA Center website ( <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a> )
Knowledge Assessment	N/A	N/A	N/A	
Benchmark Cases	N/A	N/A	N/A	
Phantom Irradiation	X	X	X	A liver phantom study provided by the IROC Houston QA Center must be successfully completed. Instructions for requesting and irradiating the phantom are found on the IROC Houston web site ( <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a> ). Note that only the most sophisticated technique needs to be credentialed, e.g., if credentialed for IMRT, 3DCRT may be used. VMAT, Tomotherapy, Cyberknife and proton treatment delivery modalities must be credentialed individually.
IGRT Verification Study	X	X	X	The institution must submit a sample of verification images showing their ability to reproducibly register daily IGRT information with a planning CT dataset (i.e., the GTV falls within the CT simulation defined PTV). The patient ("as if patient") used for this study must have a target (or mock target) in the liver. The information submitted must include 2 IGRT datasets (from 2 treatment fractions) for a single patient and must employ the method(s) that will be used for respiratory control for patients entered from a particular institution (e.g. abdominal compression, breath hold, etc...). This information with a spreadsheet (the spreadsheet is available on the IROC Houston web site, <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a> )
Pre-Treatment Review	X	X	X	The first patient to be enrolled from each institution will be planned per NRG-GI001 specifications and submitted via TRIAD for evaluation by the IROC Houston QA Center and the trial PI or designee. Feedback will be given to the institution within 3 business days regarding any concerns prior to the patient being treated. Any required treatment plan modifications must be resubmitted for evaluation prior to treatment.
<b>Credentialing Notification Issued to:</b>				
Institution				IROC Houston QA Center will notify the institution and NRG Headquarters that all desired credentialing requirements have been met.

# Websites to find Credentialing Requirements

- <http://irochoouston.mdanderson.org>  
(<http://rpc.mdanderson.org>)

The screenshot shows the IROC MD Anderson website. The header includes the IROC logo (IMAGING AND RADIATION ONCOLOGY CORE) and the text "MD Anderson IROC Houston Quality Assurance Center". A search bar for "IROC Houston by Google" and the phone number "Tel: 713-745-8989" are present. The navigation menu includes "Home", "Credentialing", "Participating Institutions", "IROC'S New Participant Demographics Form", and "Facility Questionnaire". The main content area is divided into several sections: "IROC QA Centers" with links for "IROC Ohio", "IROC Philadelphia", "IROC Rhode Island", and "IROC St Louis"; "Clinical Trial Reorganization" with links for "TRIAD" and "NCTN Structure Name Library"; "IROC Announcements" with links for "TG-142" and "Heterogeneities"; "Protons in Clinical Trials" with links for "NCI guidelines" and "Proton Approval"; and a "Services" section with buttons for "MDADL", "ADCL", "RDS", "EORTC", "Zeria / CMIC", "Short Courses", and "US Oncology". A text block describes the M.D. Anderson Dosimetry Laboratory's calibration services.

<http://www.irocqa.org>

The screenshot shows the IROC website homepage. The header includes the IROC logo (IMAGING AND RADIATION ONCOLOGY CORE) and the text "Global Leaders in Clinical Trial Quality Assurance". It also mentions "Administered by the American College of Radiology" and the "ACR RADIOLOGY" logo. A search bar and navigation menu with links for "About Us", "Services", "Trial Credentialing", "Resources", and "News & Events" are visible. The main content area features a large image of two people working with a circular device, likely a dosimetry phantom, inside a radiation therapy machine. To the right of the image is the text "Global Leaders in Imaging and Radiation Oncology Clinical Trial Quality Assurance".

# Specific Protocol Requirements



MD Anderson

IROC Houston Quality Assurance Center

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[Home](#) [Credentialing](#)

[Participating Institutions](#)

[IROC'S New Participant Demographics Form](#)

[Facility Questionnaire](#)

## NRG BR001 Requirements

This trial will utilize TRIAD for dosimetry digital treatment data submission. TRIAD is the American College of Radiology's (ACR) image exchange application and it is used by the NRG. See [here](#) for information on installing TRIAD.

In order to complete the **SBRT credentialing** process, the following items must be completed:

- All participants are asked to complete the [Facility Questionnaire](#).
- All participants are asked to complete and submit a [Specific Benchmark Plan](#). Click [here](#) for the DICOM structure file for CyberKnife.
- Successfully complete the IGRT credentialing study. Details can be found [here](#). (Click [here](#) for IGRT data spreadsheet).
- Irradiate the IROC Houston's SBRT phantom. Please fill in the [request form](#) online.
- Pre-Treatment Review is needed. See section 6.0 of protocol for details.

Note:

- Institutions that were previously credentialed to participate in another SBRT protocol or have a question about your status for this protocol, please fill out the [credentialing status inquiry](#) form.
- Click [here](#) to access the DVA being used to evaluate all BR001 patients.
- [Frequently Asked Questions](#)

# What is the best place to find SBRT credentialing requirements?

20% 1. <http://www.irs.gov>

20% 2. <http://www.cancer.gov>

20% 3. <http://irochouston.mdanderson.org>

20% 4. <https://www.nrgoncology.org>

20% 5. <http://atc.wustl.edu>

<http://irochouston.mdanderson.org>

- Followill, et al, Credentialing for participation in clinical trials, *Frontiers in Radiation Oncology*, vol. 2, p 1-8, article 198, 2012.



# Facility Questionnaire

## Facility Questionnaire (Demographics and Technical Survey)

All textboxes are editable. Please review the data below verifying its correctness. If data is missing or changes are required, please make the modifications or additions. Use the appropriate  to periodically register your changes. **Please make sure to click the Submit the Facility Questionnaire button at the end of the form to verify that the information is correct to the best of your knowledge and to close out the form.**

*\*Note: Please fill in as much as you can and submit. You can always fill out the rest or make changes at a later time.*

### General Institution Information

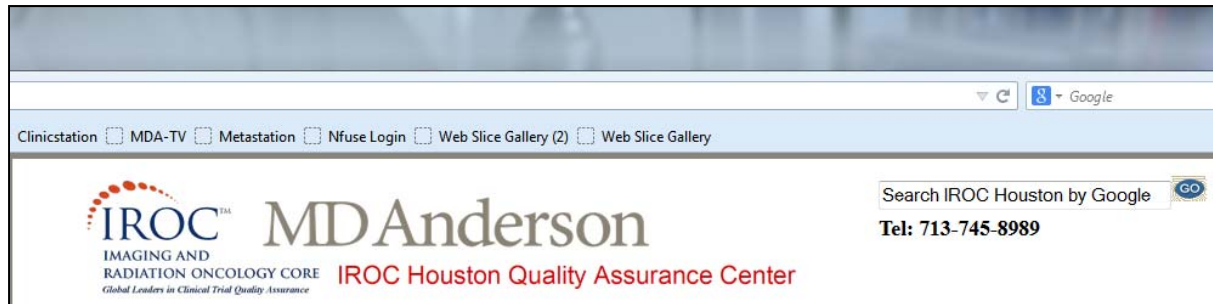
Institution Name:	<input type="text" value="M D Anderson Cancer Center"/>		RTF#	<input type="text" value="1744"/>	
Address	<input type="text" value="Department of Radiation Physics"/>		Last Accessed:	<input type="text" value="Mar-09-2015 03:32-PM"/>	
	<input type="text" value="1515 Holcombe"/>		CTEP/NCI Id#:	<input type="text" value="TX035"/>	
City	<input type="text" value="Houston"/>		Today's Date	<input type="text" value="27-May-2015"/>	
State	<input type="text" value="TX"/>	Country	<input type="text" value="USA"/>	Zipcode	<input type="text" value="77030"/>
Telephone:	<input type="text" value="7135632500"/>	Extension:	<input type="text"/>	Fax:	<input type="text" value="7135632545"/>
Person submitting this form	<input type="text" value="-"/> <input type="text" value="Michael"/>	<input type="text" value="Gillin"/>	Degree:	<input type="text" value="PhD"/>	
Email	<input type="text" value="mgillin@mdanderson.org"/>	Phone	<input type="text" value="713 563 2507"/>		

*If you are participating in the IROC Houston QA program, please confirm the TLD/OSLD and billing address form by clicking the OSL/BILLING button*

List the **primary** individuals responsible for general question regarding clinical trials and dosimetry compliance (OSLD/TLD monitoring) for NCI sponsored clinical trials.

	<u>First Name</u>	<u>Last Name</u>	
Physicist	<input type="text" value="Dr."/> <input type="text" value="Michael"/>	<input type="text" value="Gillin"/>	Degree: <input type="text" value="Ph.D."/>
Email	<input type="text" value="mgillin@mdanderson.org"/>		Phone <input type="text" value="713-563-2507"/>
Fax	<input type="text"/>		

# Credentialing Status Inquiry (CSI) Form



**Please note: You will be contacted via email or phone within 2 business days. Once we determine that all requirements are met, a credentialing letter will be issued within 5 business days.**

and the study group of your status. The study group or IROC Houston will inform your institution when it can participate in the requested protocol. If you have any questions, please contact IROC Houston at (713) 745-8989 or [IROCHouston@mdanderson.org](mailto:IROCHouston@mdanderson.org)

**Please note: You will be contacted via email or phone within 2 business days. Once we determine that all requirements are met, a credentialing letter will be issued within 5 business days.**

Institution:  Study Group Name:

RTF#: (here)  NCI #:

Name of person completing this form:

Phone #:  Email address:

Are you a:  Radiation Oncologist  Physicist  Dosimetrist  Clinic Coordinator

Protocol to be credentialed:

Specify technique:  3DCRT  IMRT  SBRT  Proton  Brachytherapy

Treatment planning system to be used for this protocol:

Algorithm to be used for patient plans:

Has your institution successfully irradiated an IROC Houston phantom?  Yes  No

If yes, which phantom?

IMRT head & neck  IMRT pelvis  lung  liver  SRS head  Spine  Spine-Lung


For SBRT(3D-CRT/IMRT) treatments, what form of respiratory motion restriction / compensation

Time Period	Number of CSI Forms
2013	379
2014	927
Jan to March 2014	97
Jan to March 2015	420
3/1/13 – 3/1/14	411
3/1/14 – 3/1/15	1178

# Knowledge Assessment

Simply a test to verify that key details of the protocol are understood.



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[Home](#) [Credentialing](#)

[Participating Institutions](#)

[IROC'S New Participant Demographics Form](#)

[Facility Questionnaire](#)

## CREDENTIALING FOR NRG BN001 KNOWLEDGE ASSESSMENT QUESTIONNAIRE

This questionnaire is intended to evaluate your understanding of the protocol. If there are any questions please contact the IROC Houston at (713) 745-8989 or [IROCHouston@mdanderson.org](mailto:IROCHouston@mdanderson.org)

Facility Name:

Provide the Facility's member number. RTOG #:  RTF#:

Name of Radiation Oncologist completing this form:

Email address of Radiation Oncologist:  Phone Number:

Name of Physicist:  Phone Number:

Email address of Physicist:

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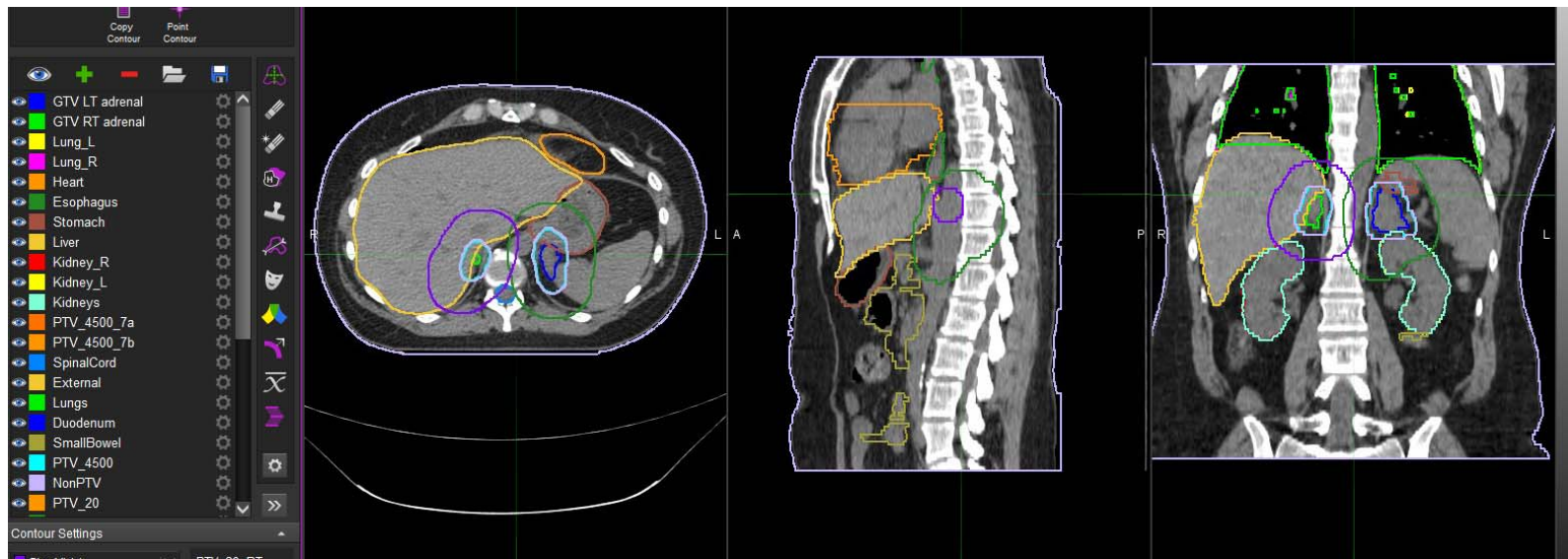
1. Patients in the proton arm will be treated to a dose of  Gy(RBE) in  fractions with a simultaneous integrated boost to  Gy(RBE) in  fractions.

2. A diagnostic contrast-enhanced **MRI** of the brain must be performed postoperatively within  hours of resection. The enhancing tumor must have a maximal diameter of  cm.

3. All proton centers must be able to deliver photon therapy or partner with a photon therapy site for patients randomized

# Benchmark Cases

- CT datasets requiring contouring (sometimes) and treatment planning according to the protocol.
- Most often these cases are required by study PI.
- Trying to not use these since everyone submits a case to be evaluated but never puts patients onto the trial.
- Trying to transition to using the first patient submitted from each institution having a pre-treatment review



# Lung SBRT - Heterogeneity Correction Algorithms

- Must use the acceptable algorithms

## Acceptable

Brain Lab / Monte Carlo Eclipse / AAA  
Eclipse / ACUROS  
Pinnacle / Collapsed Cone Convolution –  
Adaptive Convolve XiO / Superposition – Fast  
Superposition  
Monaco / Monte Carlo  
Helax / Collapsed Cone  
TomoTherapy / Convolution Superposition  
Corvus / Monte Carlo Multiplan / Monte Carlo  
In House TPS / Monte Carlo

## Unacceptable

Brain Lab / Pencil Beam Eclipse / Pencil Beam  
Pinnacle / Fast Convolve  
XiO / Modified Clarkson – Convolution Helax  
/ Pencil Beam  
Corvus / Pencil Beam Multiplan / Ray Tracing  
In House TPS / Pencil Beam or Clarkson base

Which of the following classes of heterogeneity correction algorithm is not acceptable for lung SBRT in NCI funded clinical trials?

- 20% 1. AAA
- 20% 2. Convolution Superposition
- 20% 3. Monte Carlo
- 20% 4. Pencil Beam
- 20% 5. ACUROS

# 4. Pencil Beam

- Kry et al, Algorithms used in Heterogeneous dose calculations show systematic differences as measured with the Radiological Physics Center's anthropomorphic thorax phantom used for RTOG credentialing. *Int. J. Radiat. Oncol. Biol. Phys.*, Vol. 85, pp. e95-e100, 2013

# Phantom Irradiation



MDAnderson

IROC Houston Quality Assurance Center

Search IROC Houston by Google



Tel: 713-745-8989

Is this repeat phantom?

Yes

No

Phantom requested (Please select one):

- SRS Head
- IMRT H&N
- Proton Head
- Proton Prostate
- IMRT Thorax
- 3D CRT Thorax
- Proton Thorax
- IMRT Spine
- Proton Spine
- Photon Liver
- Proton Liver

Method to account for respiratory motion (if applicable):

Protocol to be credentialed for:

Has your IRB granted approval for this protocol?

Yes

No

Machine:

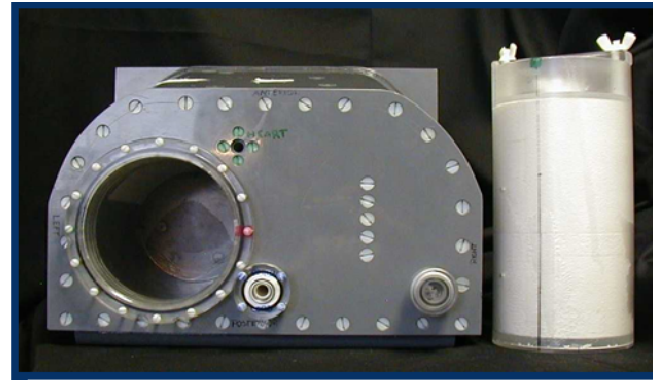
Make:



# Phantoms



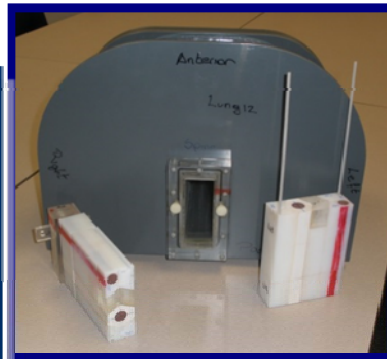
**3 prostate phantoms**



**25 lung phantoms**



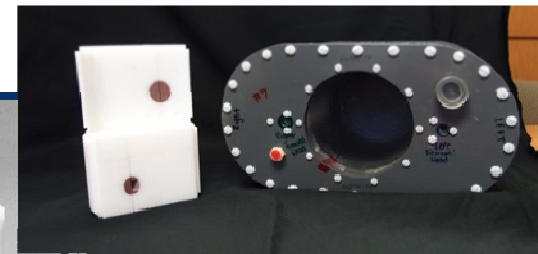
**15 H&N  
phantoms**



**8 Spine  
phantoms**

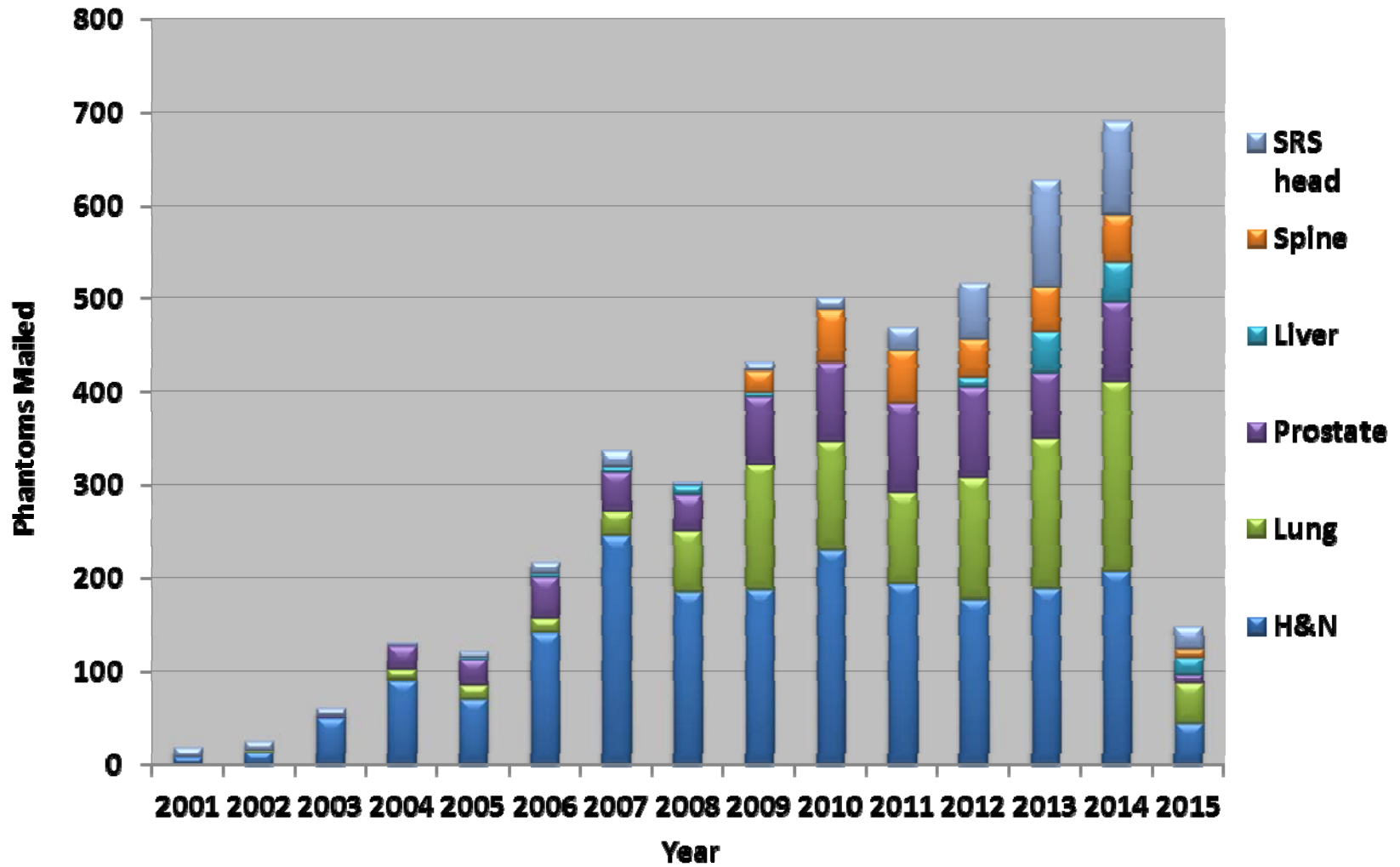


**12 SRS phantoms**



**10 liver inserts**

# Phantoms Shipped



# Phantom shipping is based on a Prioritization score

- Date of request
- IRB approval
- Completion of other credentialing requirements
- Request by study PI
- Large accruing center
- Logistical performance in the past

# IGRT

- Subdivided into anatomic regions (H&N, thorax and abdomen)
- Current method is to
  - describe technique used,
  - provide image files displaying the registration from 2 consecutive treatment fractions
  - complete a spreadsheet of shifts performed
- IGRT credentialing is currently under review and may be modified in the future.

# Grandfathering

- We love it!!
- Goal to minimize your work and ours!
- Let the IROC Houston staff tell you if you need to do anything via the **CSI** form.



# Proton Therapy

- Two processes to using proton in NCI clinical trials
  - Approval process – institution must complete several requirements (FQ, annual beam monitoring, baseline phantoms, on site visit, electronic data transmission)
  - Protocol specific credentialing as outlined above (phantoms, IGRT, KA, etc)

# The proton center approval process includes the following except:

- 20% 1. Baseline phantom irradiations
- 20% 2. Knowledge Assessment
- 20% 3. On site Dosimetry visit
- 20% 4. Annual Beam monitoring
- 20% 5. Facility Questionnaire

## 2. Knowledge Assessment

- Guidelines for the Use of Proton Radiation Therapy in NCI-Sponsored Cooperative Group Clinical Trials, [rrp.cancer.gov/content/docs/proton.doc](http://rrp.cancer.gov/content/docs/proton.doc) , 2012



# Approval

- Once all of the requirements have been met, IROC Houston will notify all pertinent parties that the institution is credentialed via email.
- CTSU adds attribute to RSS to allow institution to enroll patients



IROC Houston QA Center  
MD Anderson Cancer Center  
8060 El Rio Street  
Houston, TX 77054  
Tel (713) 745-8989  
Fax (713) 794-1364  
Email: irochouston@mdanderson.org

April 10, 2014

Steven Frank, M.D.  
MD Anderson Proton Center – NCI #TX035; RTF #3419  
Department of Radiation Oncology  
1840 Old Spanish Trail, Unit #1150  
Houston, TX 77030

Dear Dr. Frank:

You are now approved to enter patients onto RTOG protocol 1308. You have successfully completed the Knowledge Assessment Questionnaire, update of the Facility Questionnaire, IGRT credentialing, and the lung phantom irradiation. Your institution can only use protons to treat patients placed on RTOG 1308.

You may only treat patients with 3DCRT or IMRT therapy at the following photon institution(s):  
MD Anderson Cancer Center – NCI #TX035; RTF #1744

Please do not hesitate to call me at (713) 745-8989 if I can be of any further service or if you have any questions.

Sincerely yours,

A handwritten signature in blue ink that reads "David Followill".

David Followill, Ph.D.  
Director, IROC Houston QA Center

# Summary

- There can be just a few steps or many depending on the specifics of the protocol.
  - Oligometastases protocols – complex
  - Brain protocol – simple
- Do not start the process at the last minute. Be Proactive. It takes time and effort.
- Let the team at IROC Houston help you

Thank you

Questions?