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#### Introduction

No published literature



Clinical experience (myself/Susan Richardson)

- Nucletron/Impaq (2002-2007)
- Verisource/ARIA (2007-2012)
- GammaMed/MOSAIQ (2012-present)

Input from TG-262 (EMR) questionnaire, discussion, early drafts







# Why is Brachy not like a LINAC?

- EMR is not the R&V
- Range of connectivity from none to some
- Legal constraints set by NRC (in the USA, in agreement states)
- For LDR: location of procedure in OR

But wait – does this not sound familiar?





## Many other devices are like brachy!













# Replace Brachy/External Beam With These Categories:

#### No connectivity

- LDR in OR
- Some HDR/EMR combinations
- Other devices without EMR connectivity software

#### Limited connectivity

- Some HDR/EMR combinations
- Other devices with (optional) EMR connectivity software

#### Full connectivity

(possibly) ARIA/Verisource







# Before we study these categories, let's cover the Written Directive first





#### 10 CFR 35.40 Written Directives

 (a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

#### Should Not Be Necessary to use in RadOnc



- (b) The written directive must contain the patient or human research subject's name and the following information-
  - (1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;
  - (2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;
  - (3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
  - (4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;
  - (5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
  - (6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
    - (i) Before implantation: treatment site, the radionuclide, and dose; and
    - O (ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).
- (c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.
  - (1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.
- (d) The licensee shall retain a copy of the written directive in accordance with § 35.2040.







#### 10 CFR 35.40 Written Directives

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  - [..]
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#### Written Directive for HDR

② Radiation Prescription	ns Name, MR #									×	× ¥
Dx: IIIB:	*Endocervix									Close	~
0.320.00									Course: 1	Add	
» Site	Technique	Modality	Act	Rx		ections Patte	m	Act	Rx D A	Change	
Rt inguinal bst 2 Lt inguinal bst 2	ENFACE ELECT ENFACE ELECT		5 5	5 5	200 cGy 200 cGy	Daily Daily		1,000 cGy 1,000 cGy	1,000 cGy 1,000 cGy	Delete	
Cervix1 Cervix2	HDR Interstitial HDR Interstitial	Ir-192 HDR Ir-192 HDR	2	2	700 cGy 700 cGy			1,400 cGy 1,400 cGy	1,400 cGy 1,400 cGy	Dosimetry	
•									+ <del>-</del>	<b>F ±</b>	
Rx Site: cen Technique: HDI	R Interstitial	Statu	s: App	roved J	SM 11/17		Number Fract	ions: By Cour	se 💌		
Modality: Ir-19 Dose Spec: EFF					St		Site 1 day(s) after frac	SMTW	TFSA	Note	
Rx Dose		ber of Fractionation	tion	Statu	S	٦ŀ	2	1 2 3 6 7 8 11 12 13	9 10	Plan D <u>o</u> cs	
1,400 cGy	700 cGy	2 Daily		Fract	ions Treate	ed -	3 4 5 6 7 8		19 20 24 25 +29+30	S <u>t</u> atus	ALL
Dose Limits		F	attern:	tander	m, cylinder	, 5 250	mm, 4 320mm				A The
Total Cum:		Cor	nment:	30cc t	bladder					Fx Notes	* '
		_			Rad	iation	Rx is View Only				X



#### Written Directive for LDR

#### Pre-Planning/Pre-loaded Needles:

- Pre-Implant handled like HDR
- Post-implant component done in OR

#### Live (in-OR planning): EMR Rx for Nomogram

Radiation	Prescriptions - MR#:	· · · –	-					<b>×</b>
	Dx: 0 - Not paired *		nd Gleason 3+4=	- 7			Course: 1	Close
	Adenocarcinom							Add
» Site	Technique	Mod	ality Act		actions Pattern	Act	Rx Dos Rx	Change
Prostate	LDR Brac	ythera I-125		1 14,500 cGy			14,500 cGy	
								Delete
								Dosimetry
•	I			1	1		+	<b>T</b>
Techr Moo Dose S	Site: Prostate iique: LDR Brachythe lality: I-125 Spec: min D80% Rx Fractional Dose Dose 0 cGy 14,500 cGy	Number of Fractions	Fractionation	Status Fractions Treat	Week	View Fractions: By Cour mber Fractions: By Cour S M T W	rse 💌	Note Plan D <u>o</u> cs Status
Dose Li	mits		Pattern	Special Physics	Consult			
To	tal Cum:		Comment:	Prior RT at OSH	for H&N cancer			Fx Notes
				Ra	diation Rx is View	/ Only		





## Written Directive for live plan LDR: Paper Written Directive Used in OR

Name of Patient:	
Date of Birth:	
Place Label Here	

UNIVERSITY OF CALIFORNIA, DAVIS MEDICAL CENTER SACRAMENTO, CALIFORNIA

University of California Davis Health System Department of Radiation Oncology Permanent Prostate Seed Implant Written Directive

#### **Pre-implantation:**

Treatment Site: Prostate + margin ( $\leq 5 \text{ mm}$ )

Intended number of I-125 seeds:

Prescribed Dose (mCi):

Treatment Time: Permanent

Date:\_\_\_\_\_

AU Signature:

AU Name: Richard Valicenti, M.D.

#### Post Implantation before completion of procedure:

Treatment Site: <u>Prostate + margin ( $\leq 5 \text{ mm}$ )</u>

Number of I-125 seeds implanted:

Delivered Dose (mCi):

Treatment Time: Permanent

Date:\_\_\_\_\_

AU Signature: \_\_\_\_\_

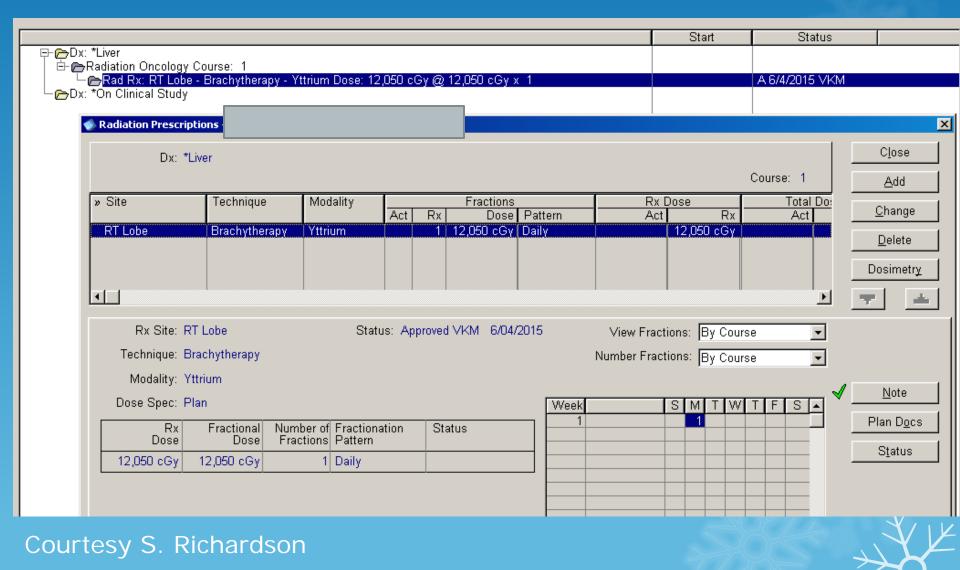
AU Name: Richard Valicenti, M.D.







#### Radiopharmaceuticals



Dadianharm cont	A K
Radiopharm, cont.	The second se
Created: 6/04/2015 VKM Edited: 6/11/2015 SLR Locked:	OK
Subject:	Cancel
F Times New Roman 💉 10 💌 🖪 🗾 🖳 🖪 🖪 🖪 🖪	
liver brachytherapy	<b>▲</b>
dosi/tx planning: 1. special physics conslut	
Radiopharmaceutical: Y-90 TheraSphere; Nordion Treatment site: RT LOBE	¥.,
Lung shunt factor: 10% Planned lung dose: 8.59 Required Y-90 activity: 5 GBQ	
Actual Y-90 activity: 5.29 GBQ	
Injection date and time: 6/11/2015 11 AM Delivered target dose: 122.9	1
Delivered lung dose: 8.76	
Total lung dose: 8.76 Maximum allowed lung dose per treatment: 30Gy	
Maximum allowed total lung dose: 50Gy	
	<b>.</b> ال

¥

#### Courtesy S. Richardson

# Are electronic signatures ok with legislators? The Theory:

Report of the Advisory Committee on the Medical Uses of Isotopes for Electronic Signatures

April 16, 2012

#### Subcommittee Members

Bruce Thomadsen, Ph.D., Chair Chris Palestro, M.D. John Suh, M.D. James Welsh, M.D.

#### Recommendation

The Subcommittee on electronic signatures endorses following the guidance of the E-Sign Act (Public Law No. 106-229), which defines an electronic signature as:

" 15 USC 7006 106 (5) ELECTRONIC SIGNATURE .—The term "electronic signature" means an electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record."

The Subcommittee further recommends that the NRC accepts as compliant electronic signatures that satisfy this specification, including, as an example, approving a document with a password or PIN or a digitized signature but not excluding other possibilities.

#### Discussion

There have been US Government standards for electronic signatures since 1999. The standards follow international protocols. The Public Law cited above follows the NIST standard. This includes approving a document with a password or PIN or any digitized signature such as common at a supermarket checkout. Actually, any mark made with the intention of signing a record is legitimate.

Public Law
 106-229 as
 guidance

Departmental/ institutional policy about validation required (verbal communication Linda Kroger)





# Are electronic signatures ok with legislators? In Practice:

- Public servants have wide range of comfort level with EMR (they are just like us)
- Talk to them <u>before</u> you implement EMR (preempts surprises at your next State Inspection)
- If they have questions, point them to Public Law 106-229 and your policy
- Address their concerns; regulators are usually helpful folks who want to help you be informed.





# Back to the 3 Categories of EMR Connectivity

- 1. No connectivity
- 2. Some connectivity
- 3. Full connectivity (Note: will not cover in detail, same as linac except written directive)



#### Delivery Devices configured with "No Connectivity"







#### What workflow is same on LINAC?

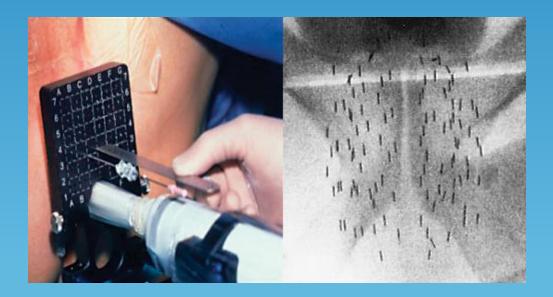
- Simulation
- Prescription
  - Not connected to planning even for integrated systems!
  - Should be filled out/signed before planning starts
- Treatment plan documentation
- Checklists used during the process





## What is different from LINAC?

Process diverges *after* Tx plan is approved
Treatment delivery workflow differs
Some convergence for weekly QA
Converges at final chart check







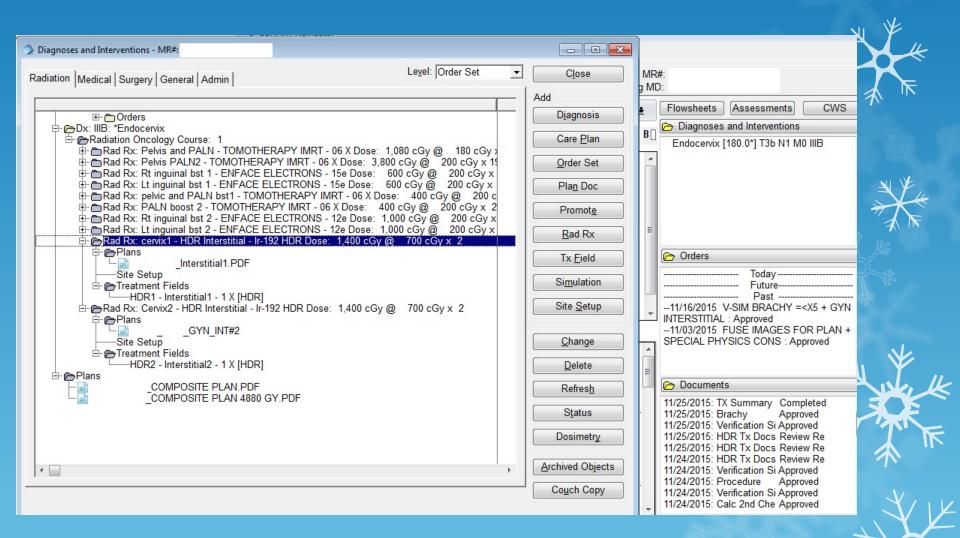
### Solution for Delivery Workflow

- Treatment Documentation:
  - Pre- and post treatment verification on paper
  - Pre-treatment checklist on paper
  - Scan paper into EMR after treatment
- Define documentation destination similar to linac workflow
- Set time by when scan has to be completed
- Manually create treatment "path" before Tx starts
- ✤ Record treatment IMMEDIATELY after Tx completion ◄
- Verify documents and dose record at weekly & final chart checks





#### Example: UCD HDR





# Example: UCD LDR

Diagnoses and Interventions - MR#:					N	¥
Radiation Medical Surgery General Admin	Lev	el:  Order Set			⊐ ≯	
Orders     Orders     Orders     Orders     Ox: 0 - Not paired *Prostate Gland     Ox: 0 - Not paired *Prostate Gland     Ox: 0 - Radiation Oncology Course: 1     Ox: 0 - Radiation Oncology Course	4,500 cGy @ 14,50	)0 cGy x 1				
INTRAOP TXPLAN FOLL REPORT.PDF			Status	Dictated By	Approved	Approval Date
INTRAOP VERIFICATION PLAN SIGNED IN	OR.PDF		Approved	Valicenti,	Valicenti,	11/19/2015
NEEDLES IN.PDF			Approved	Valicenti,	Valicenti,	11/23/2015
WRITTEN DIRECTIVE.PDF			Pending			
	10/13/2015	Phys Consult Report	Cosign Required	Dieterich,	Dieterich,	10/13/2015
	10/13/2015	Plan Document	Pending			
	10/13/2015	Plan Document	Pending			
	10/13/2015	Plan Document	Pending			
	10/13/2015	Plan Document	Pending			,
	10/13/2015	Plan Document	Pending			5
	10/13/2015	Treatment Plan	Approved	Valicenti,	Valicenti,	10/13/2015
	10/13/2015	IP Brachy Prostate	Approved	Valicenti,	Valicenti,	10/13/2015
	9/29/2015	PSI Source Estimate	Cosign Required	Dieterich,	Dieterich,	9/29/2015
	9/16/2015	Consent	Review Required	Carrillo, M		
	9/16/2015	OP/OId Pt SP Note	Approved	Valicenti,	Valicenti,	9/16/2015
	9/16/2015	Sim Pre-Scan	Approved	Valicenti,	Valicenti,	9/16/2015
	7/29/2015	OP/Old Pt SP Note	Approved	Valicenti,	Valicenti,	7/31/2015
	4/23/2015	OP Consult Note	Approved	Valicenti,	Valicenti,	4/27/2015
	3/3/2015	Pathology Report	Review Required	Wood, Cyn		

#### Delivery devices configured with "Some Connectivity"







#### Typical Connectivity Functions (Mileage may vary)

Scheduling

Patient demographics

Total delivered MU

These are the same as for linac! Use the synergy for workflow design





#### **Connectivity Workflow: ARIA**

- Patient is scheduled in EMR
- Patient checks in
- Treatment plan now made available on delivery machine
- EMR is updated with dose delivered at the end of fraction

w Appointme		Day View	Work Week	Week View	Month View	
ew Agenda	Monday, Febr	uaru 28, 2011	Tue	sday, March 01, 20	111	
	0210147 · F			0210147 - RadOnc		
8						
9_00						
10_00			_			XX
1-00						
12 <sup>_pm</sup>						
1_00						
2-00	SPRW_410_Test3,	Firstn (DummilD				
3-00	a 11 m_410_1683,	r son (o anniyio .				
4_00						N
					JK.	Y
					X	
						$\mathbf{X}_{-}$
						★



#### **Connectivity Workflow: MOSAIQ**

- Patient is scheduled in EMR
- Patient checks in
- Treatment plan now made available on delivery machine
- EMR is updated with dose delivered at the end of fraction

•	Treatment Chart - MedRc	:: DummyID3	SPRW_0410_1	fest3, Firstn					
	Dx:					Attending Course		a	Close Tx Calend <u>a</u>
	Rx Site: Site1 Dose: ?????/0 cG	Υ		Fractions: ??/D		Start Tx:	Approved: Last Tx:	٩	Summary Notes
	Field: H Type: H	lelical	Plan_01	ħ	ic Treatment: Machine Aachine: 0210147	Verification Exter	Stf. ZZZ	13.65	<u>I</u> reat
	En/Modality: Seconds: 10			Dose: 0 cGy		T inherenz			QA Mode
	Tx Note:							q	
	Session No Date Time I		Seq PI	Setup / Field Meterset	Dose Machine	Notes Sts TSPFDC	Вγ		
	B- 1 2/28/2011 13:55 1 13:55 ⊨	IFId HELIC		105.960 Secs	0210147	S	777		
		I. I.	l	,L L	I.	ļļ_	Į.	2	









#### There is always a caveat ...

**Note:** At the end of treatment, if registration was performed, and the machine is licensed for OIS, a copy of the Registration Screen will be attempted to be sent to the OIS. Currently, both MOSAIQ<sup>®</sup> and ARIA<sup>®</sup> do not accept this type of DICOM object.

The export screen is only available at this time. It will not be available during a review process.

- Good example of keeping customer informed
- Get list of existing tools before making purchase decision
- Each clinic has to design best workaround workflow depending on your documentation needs
- Encourage vendors to participate in IHE-RO connectathons!

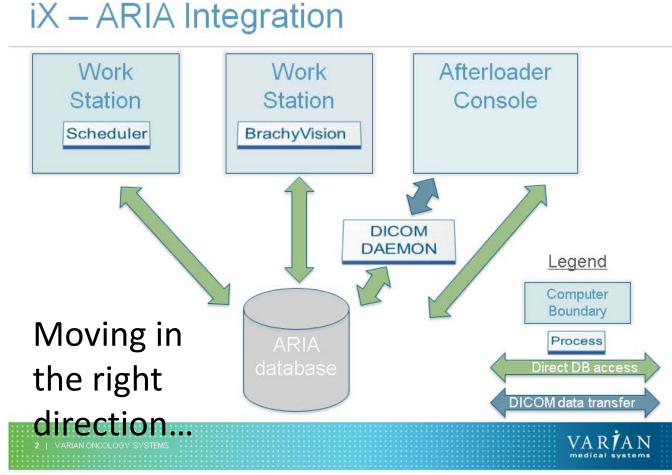






# Full Connectivity: ARIA/Varisource iX

RAD 4145b 2013-01









Afterloaders

Courtesy S. Richardson

# Brachy HDR Workflow

15 |

RT Summery	RT Summary	
a Bachy mana, tracky mana; Q Benine Brachy f		0
	Caurue Trinetinio       Practicy marmo         Prescription       © Birdchdate: Age         Trientine Diversed: 2013 Adv       © Didthdate: Age         Prescription       © Didthdate: Age         Trientine Club       © Didthdate: Age         More Details       © Personalize:         Overnoet/Exec       • Olagonosis (0)         Triendin       Clinical Alerts         Allergies: Currently unavailable       • Imaging         Patient Alerts       • Chart QA         Currently unavailable       • Chart QA	Delivered dose appears in RT Summary
34 0y	Course Summary      C1     Active      Intent     Unknown      Pan     Pert     None     None     Teatment Sign Of User     physicist     a	& Patient Summary
Home Currently unavailable Work Currently unavailable Mobile Currently unavailable Currentl Medications Currently unavailable Imaterial	34 Gy       Bef Point       Planned       Dose       Dose to date       None       34       34       Gy       Delivered       Planned       Overdose	







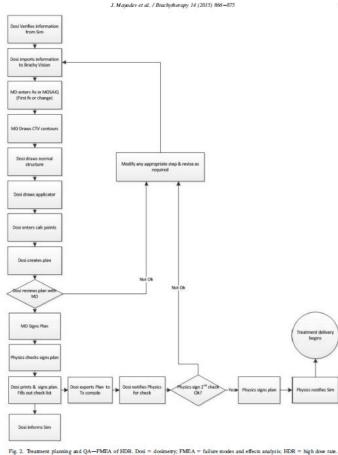
# Safe use of EMR for Brachy/Similar Devices





#### Workflow

#### 1. Have one!



#### 2. Document it!



869

Radiation Oncology Department → P&Ps → ... HDR Brachy

HEALTH SYSTEM UC Davis Radiation Oncology Department Policies & Procedures

Radiation Oncology Depart	ment IT Li	iaison Protocols Vendor Notifications Residency Programs
Libraries	🗌 Туре	Name
P&Ps		SAVI
Knowledge Base	<b>(11)</b>	Breast Interstitial Checksheet
Clinical How-to	() ()	Default Channel Assignments
Calendars	<b>(</b>	GammaMed HDR Brachytherapy Procedural Pause
Department Master	1	GammaMed HDR Cylinder Simulation
Calendar	1	GammaMed HDR Daily Check Procedure
Admin Time Away	P)	GammaMed HDR Daily Check Sheet
Physics Time Away	(P)	GammaMed HDR Documentation Flow for Electronic Charting
Tumor Board Calendar	(m)	GammaMed HDR Emergency Procedure
Physician On Call Schedule		GammaMed HDR General Procedure
	1	GammaMed HDR Planning Procedure for Tandem and Ring Applicator
Sites	(P)	GammaMed HDR Procedure for Using Nucletron Shielded Cylinders
Vendor Notifications	e la	GammaMed HDR Treatment Check Procedure
Protocols	1	GammaMed HDR Treatment Check Sheet
IT Liaison	E	Gyn Interstitial Template
People and Groups	2	HDR Prescription Policy

#### Workflow Alternatives



Network down

\* XRT:

- treat from a local file OR
- send (some) patients home
- Brachy/Other devices:
  - Plan transfer from TPS to machine via USB/sneakernet
  - Manually enter brachy plan on console from TPS printout
  - Both procedures need to be <u>commissioned &</u> <u>documented</u>









### Workflow Safeguards May Differ

- External beam has build-in safety measures in the R&V
  - Cannot treat without approved prescription
  - Cannot treat without physician & physics plan signatures
- These do not work on partially connected or unconnected devices
- Need to find alternative safeguards
- OR environment can be rushed
  - Post-implant written directive while everyone is rushing to finish procedure



# Safeguard: Using QCL checklist in MOSAIQ

Quality Checklist - MR#: 5551212 TESTY, TE	ST		
/iew: By Patient		Patient: TESTY, TEST 5551212	
» Due al Procedure	Req Resp	% Ittending M S of Comment	Close
6/18/2015Physics- 2nd check6/18/2015Prescription signed6/18/2015Appl. tip correct6/18/2015Channels per protoco6/18/2015Matches template6/18/2015Conformance < 10%	SD PHY	DS       Rx complete and approved by attending         DS       Plan approved by dosimetrist and attending         DS       Applicators defined correctly; ring offset applied         DS       Channel assignments per departmental protocols         DS       Interstitial: channel assignment matches template         DS       Planned dose same as Rx dose; point doses & DVH OK         DS       SAVI: air volume < 10% PTV_Eval volume	<u>A</u> dd <u>C</u> hange <u>D</u> elete <u>Complete</u> <u>Append</u> Due Date Range F <u>r</u> om: <u>6/15/2015</u> <u>6/19/2015</u> Filter By <u>○</u> Complete <u>◎</u> Incomplete <u>○</u> <u>A</u> ll



# Safeguard: Using Checklist Document in ARIA

Patient	Name:	Date:	
MRN:		Site/Technique:	
MD:		Nurse:	The second se
Patient	Identification:	Fraction # of	
	ent Planning Checks:		N N
Mosaiq	Written directive is signed and dated by author	rized user:	$\rightarrow$
Brachyv	vision Treatment plan- number of catheters and	l lengths correct:	The second secon
Brachyv	vision Treatment plan dose matches written dire	ective prescription:	
MU che	eck performed if treating from non-standard pla	n:	
Pre-Tre	atment checks		
	Daily QA performed:		
	Brachyvision Treatment plan transferred to Ga	mmaMed afterloader correctly:	
	Patient was connected to afterloader and chec	ked by 2 individuals:	
	Calculated treatment time matches afterloade	r:	
	= Decay Factor x treatment planning = x = 0	time = Total Time	
	GammaMed wheels locked:		$\checkmark$
	Treatment plan approved in Mosaiq by authori	ized user:	

# Safeguard: Using Questionnaire in ARIA



- Checklists (Questionnaires)
- Questions, responses and timestamps all stored in DB

1<sup>st</sup> Day of Treatment

MLC	
💽 Yes 💭 No	
Block	
C Yes C No	
Check MUs	
🔽 Check field parameters	
✓ Treatment field energies	
🔽 Field Portal/IGRT/Electron Photo Images Taken	
🔽 Take and Import Treatment Field Photos into ARIA	
🔽 Physicians Intent Reviewed by Attending	
Consent Signed?	

Chart	Rounds

Stanford Patholo	)gy		
Yes	C No	C N/A	
Staging sheet			
🙆 Yes	C No	C N/A	
🔽 Radiation the	rapy treatmen	t consent	
🔽 Radiation the	rapy treatmen	t summary	
		71 T	Tr
		$\mathbf{v}$	

### Testing the Workflow

Remember E2E tests from Radiosurgery?

#### Definition from Techopedia:

"End-to-end testing is a methodology used to test whether the flow of an application is performing as designed from start to finish. The purpose of carrying out end-to-end tests is to identify system dependencies <u>and to ensure that the right</u> <u>information is passed between various system</u> <u>components and systems</u>."

#### \* 2 Steps:

- 1. Test complete procedure first; solve any issues
- 2. Send some errors through system, check if caught





#### Summary

- Design of EMR flow depends on degree of connectivity
- Designing the workflow to be most similar to linac is key
- End-to-end testing is an essential tool for successful implementation
- Especially for use of byproduct materials, be aware of regulatory requirements



#### Acknowledgements

Susan Richardson, Swedish Hospital

TG-262 members

Data Integrity and Electronic Charting (EBRT and Brachytherapy): Clinical Implementation of Electronic Charting – Lisa Benedetti 2013 SCM, <u>https://vimeo.com/90160027</u>

Accurate Training department for screen captures from ARIA

