Electronic Charting for Brachytherapy

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Introduction

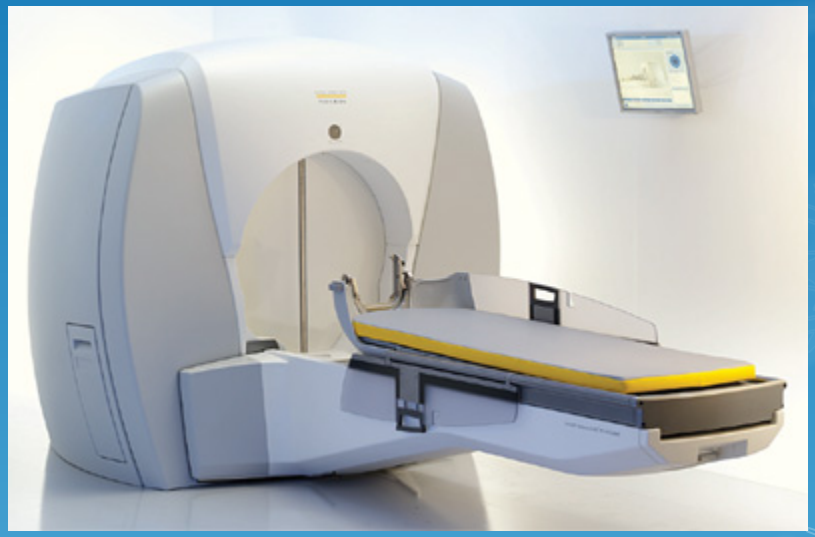
- No published literature
- Clinical experience (myself/Susan Richardson)
  - Nucletron/Impaq (2002-2007)
  - Verisource/ARIA (2007-2012)
  - GammaMed/MOSAIQ (2012-present)
- Input from TG-262 (EMR) questionnaire, discussion, early drafts

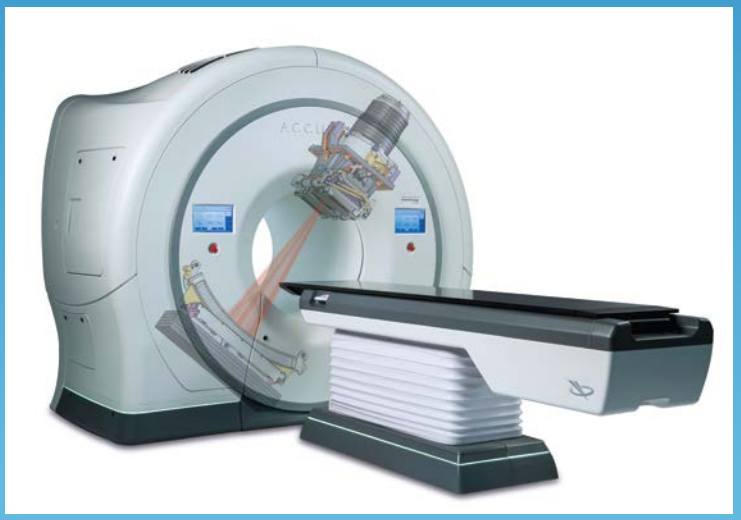
Why is Brachy not like a LINAC?

- 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
    - (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

- (a) A written directive must be dated and signed by an authorized user before the administration [...]
- (b) The written directive must contain the patient or human research subject's name and the following information-
  - [..]
  - (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
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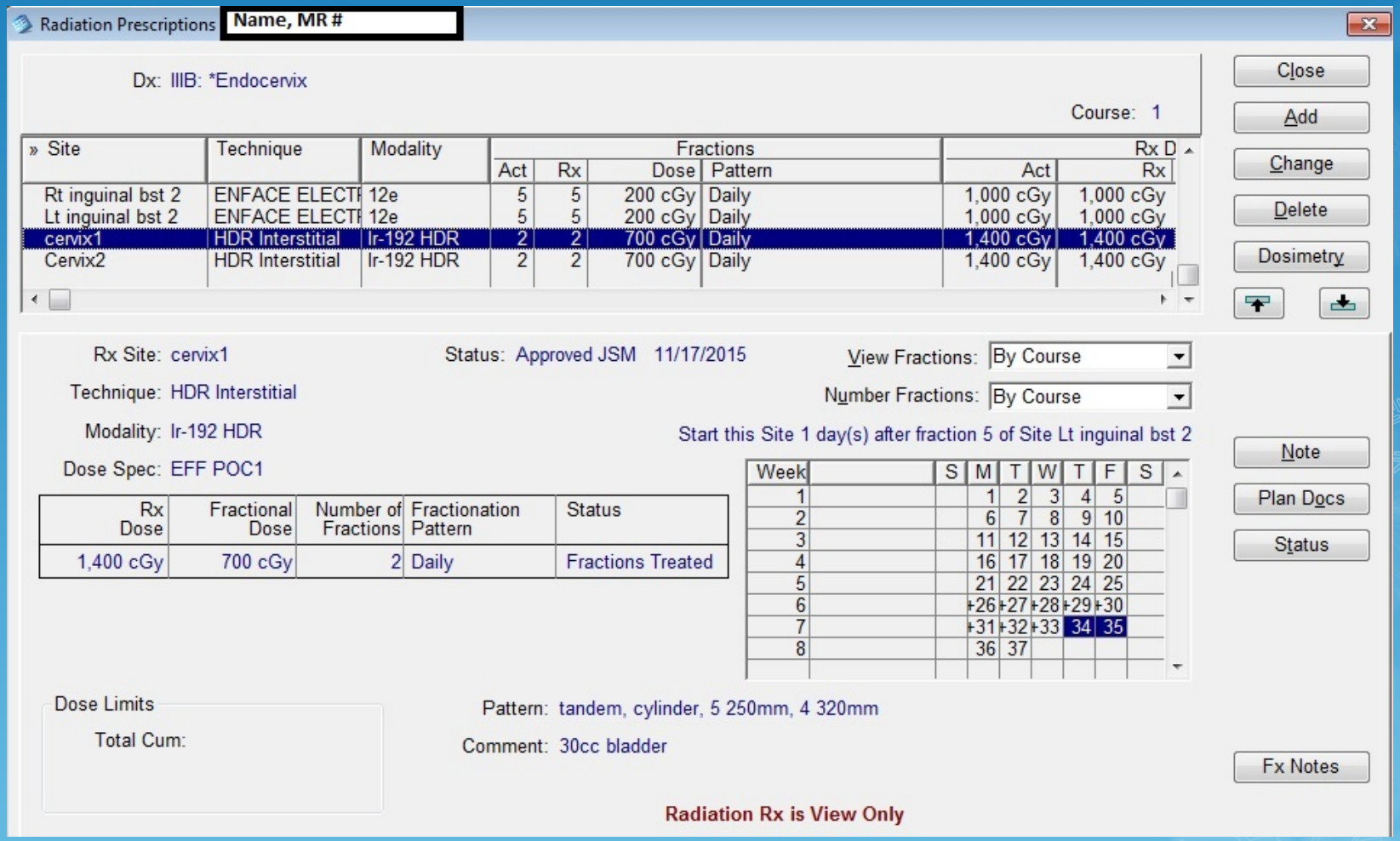
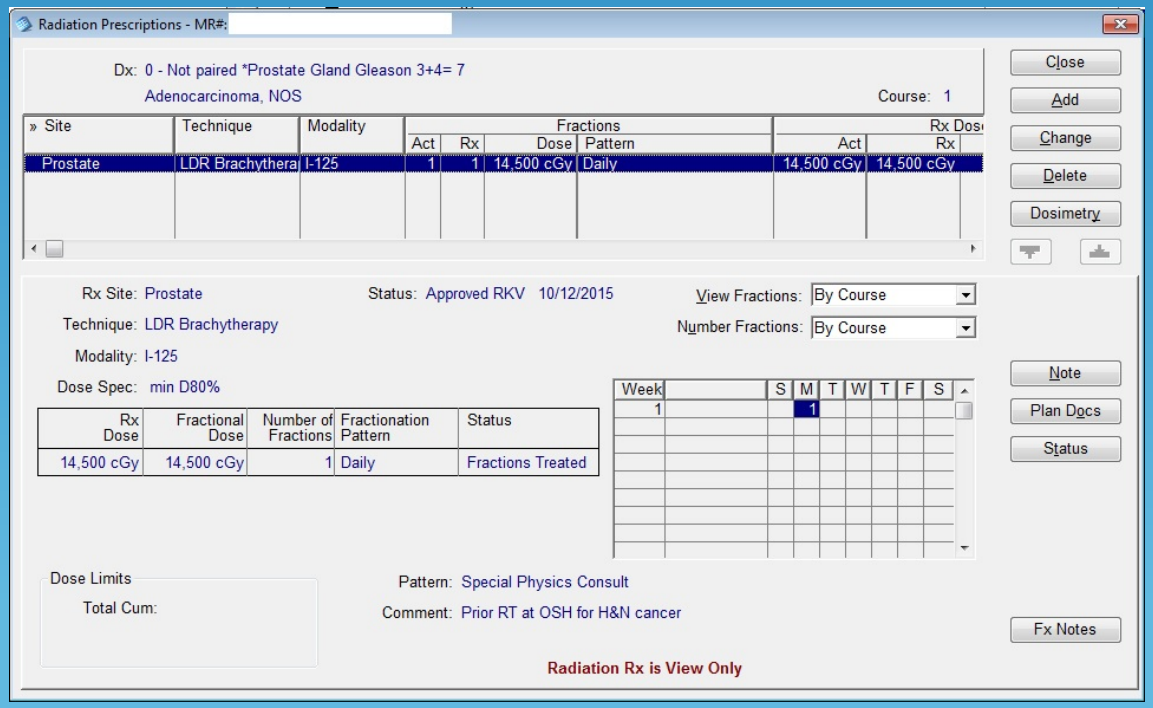
- (c) A written revision to an existing written directive may be made [..]

Written Directive for HDR



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



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

MR#: ☐☐☐☐☐☐☐
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 (≤ 5 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: Prostate + margin (≤ 5 mm)

Number of I-125 seeds implanted: _____

Delivered Dose (mCi): _____

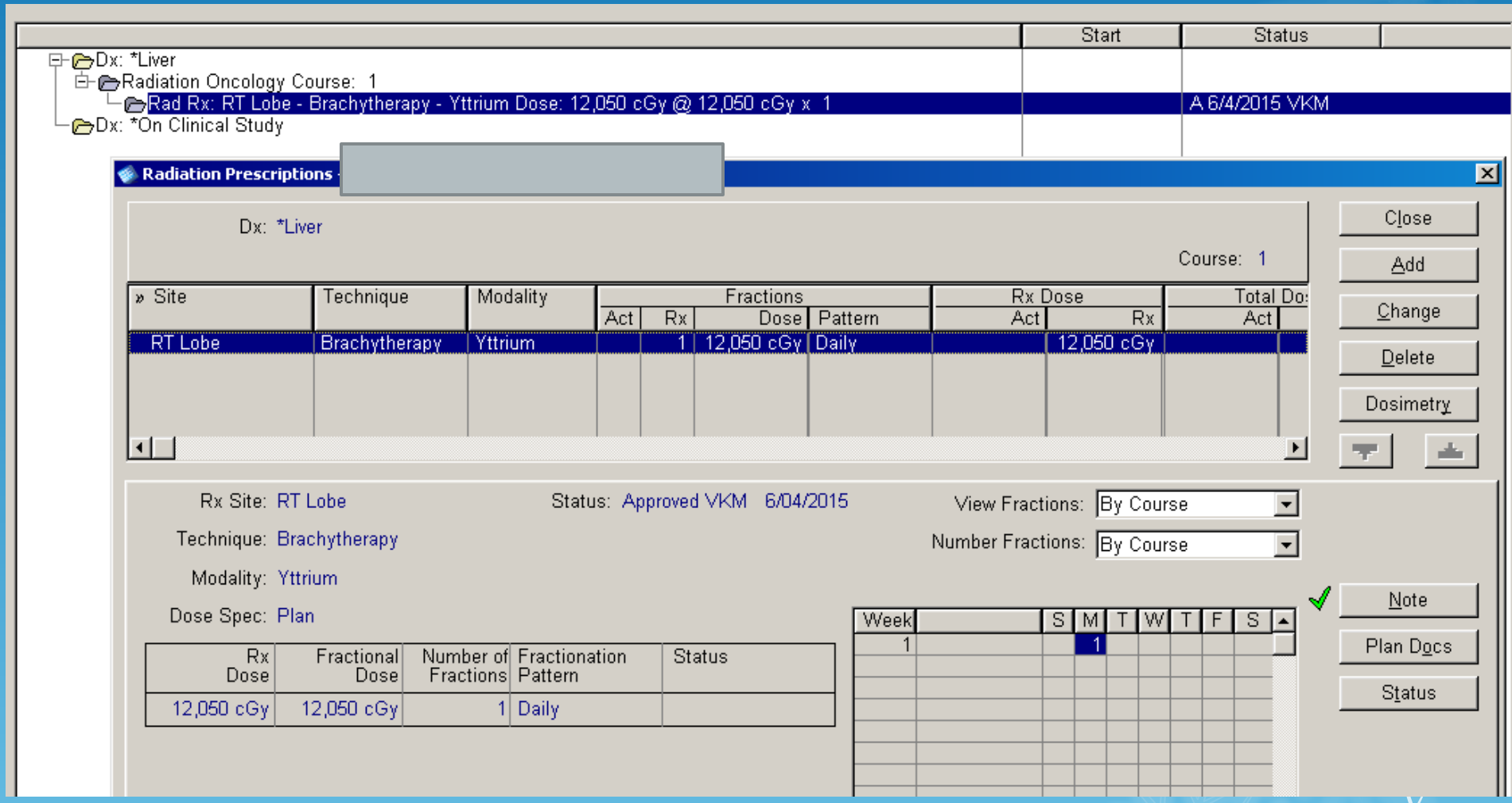
Treatment Time: Permanent

Date: _____

AU Signature: _____

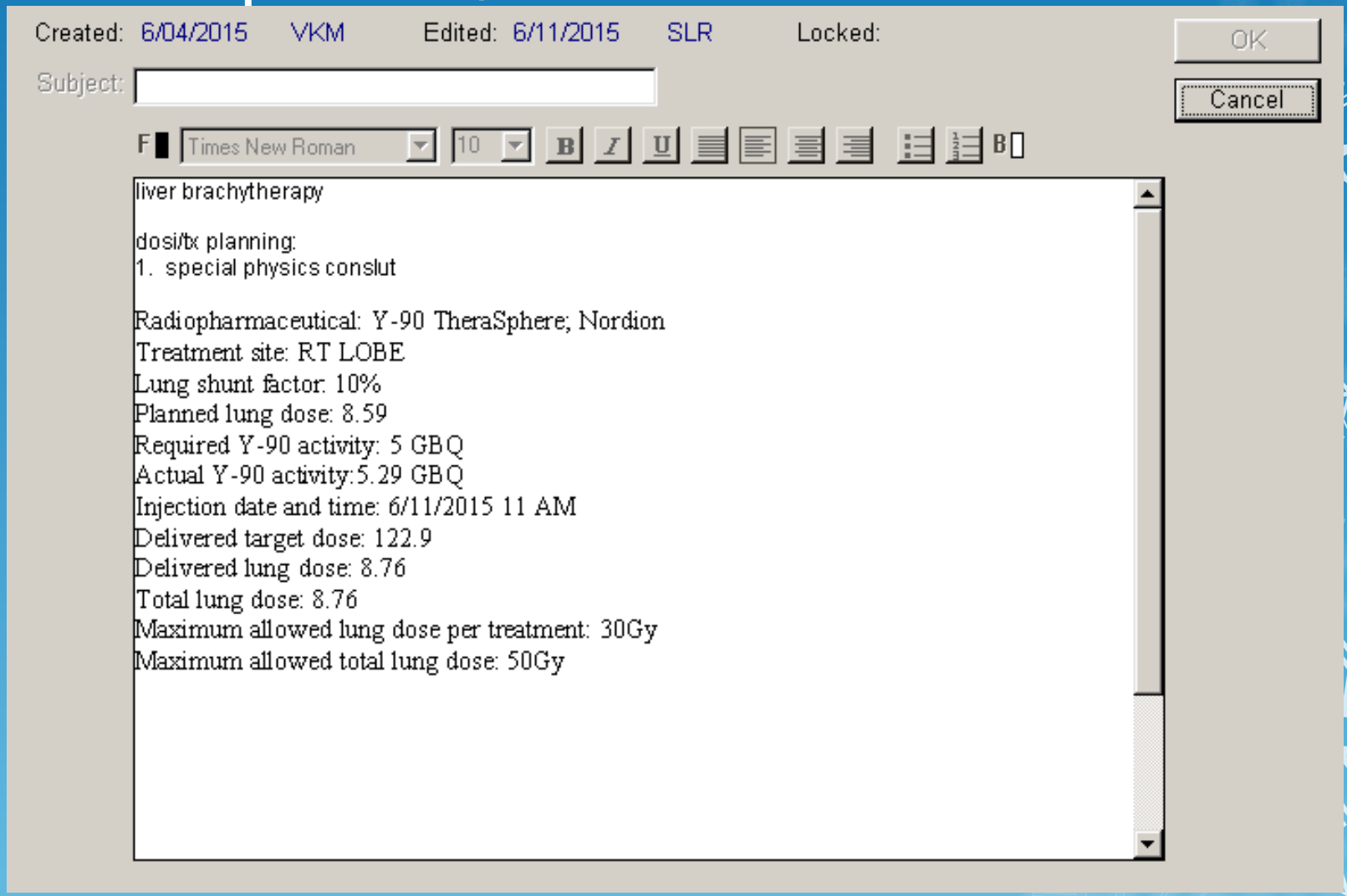
AU Name: Richard Valicenti, M.D.

Radiopharmaceuticals



Courtesy S. Richardson

Radiopharm, cont.



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)

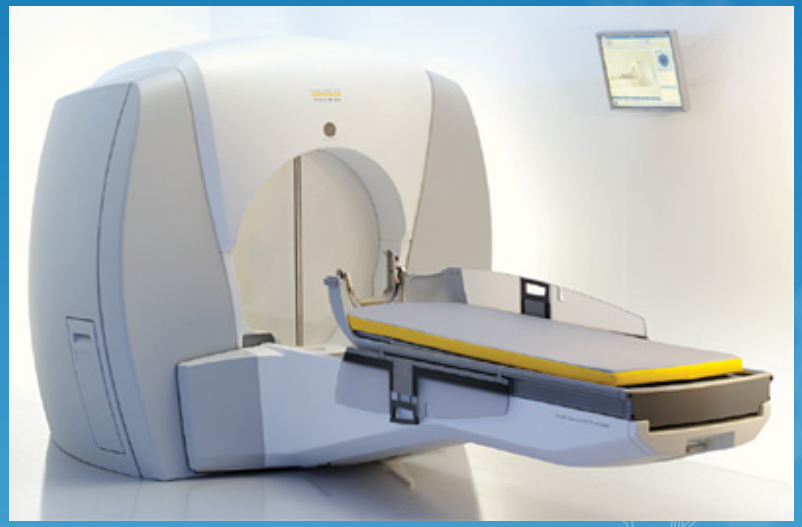
Are electronic signatures ok with legislators? In Practice:

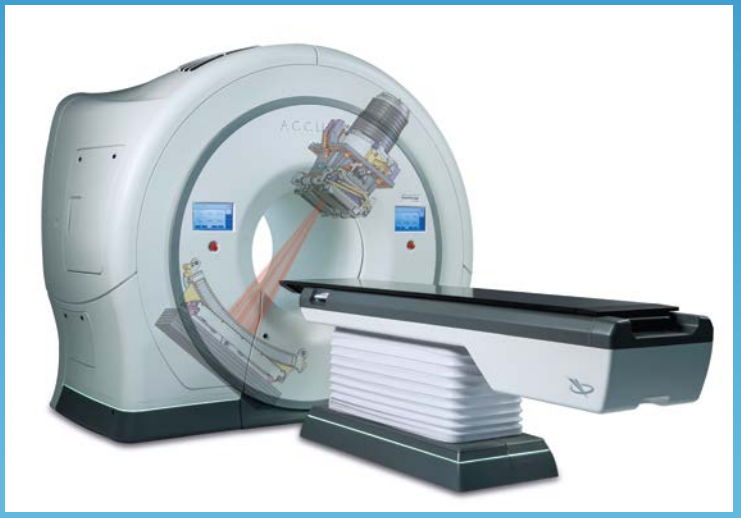
- Public servants have wide range of comfort level with EMR (they are just like us)
- Talk to them before you implement EMR (preempts surprises at your next State Inspection)
- If they have questions, point them to Public Law 106-229 and your policy
- Address their concerns; regulators are usually helpful 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”



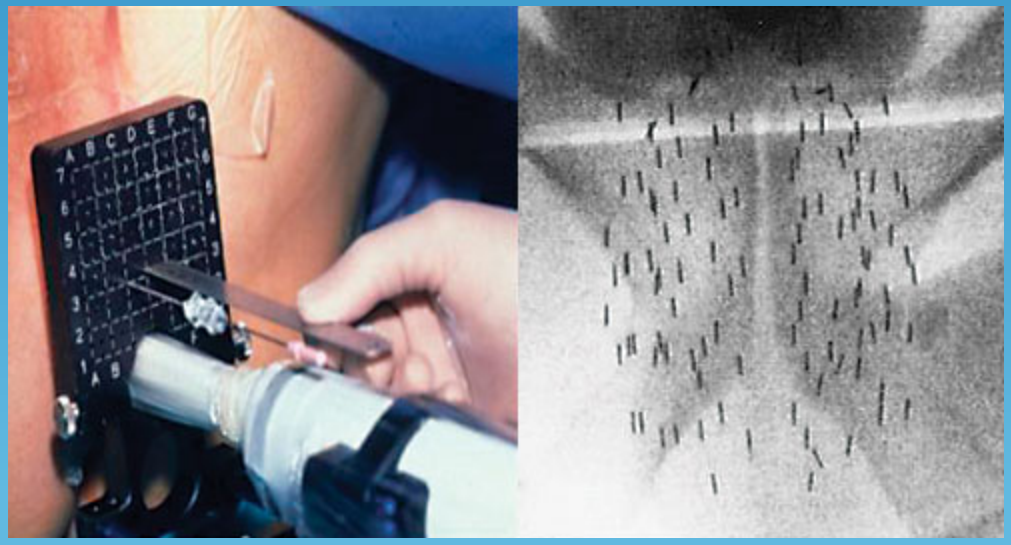


What workflow is same on LINAC?

- 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?

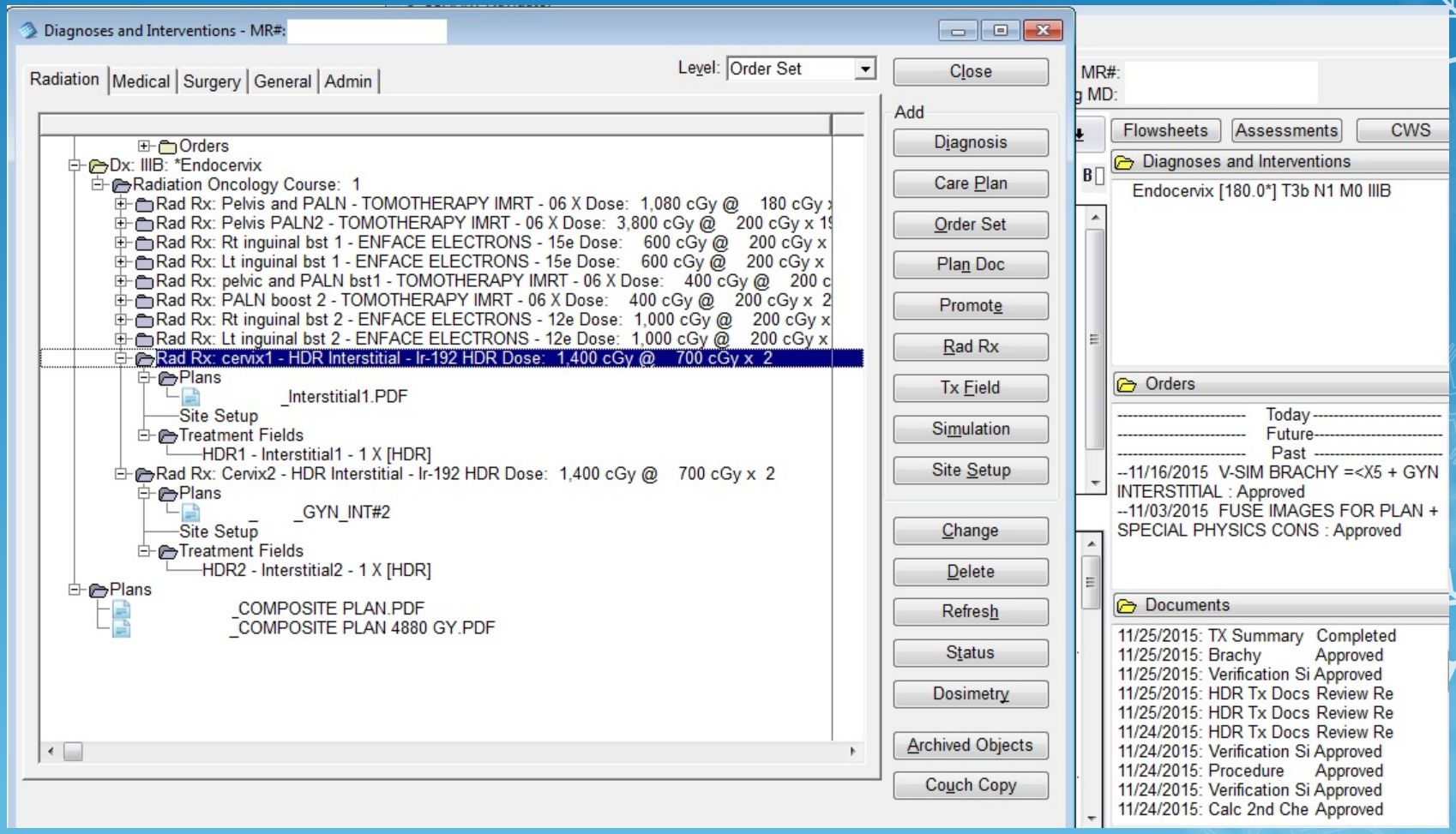
- Process diverges ***after*** Tx plan is approved
- Treatment delivery workflow differs
- Some convergence for weekly QA
- Converges at final chart check



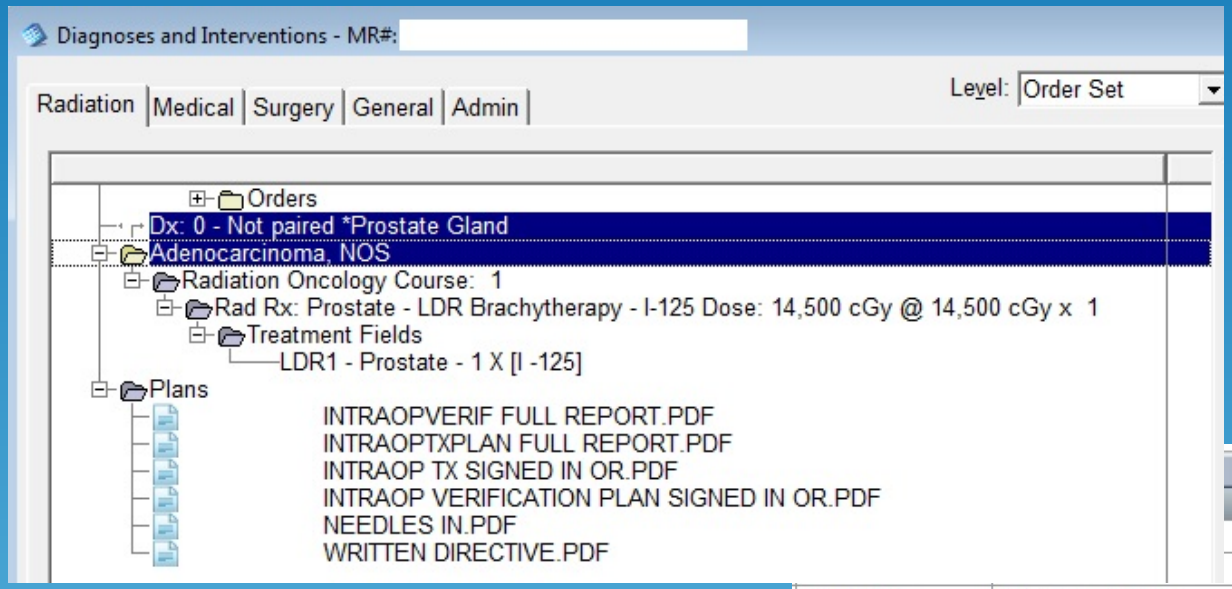
Solution for Delivery Workflow

- 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

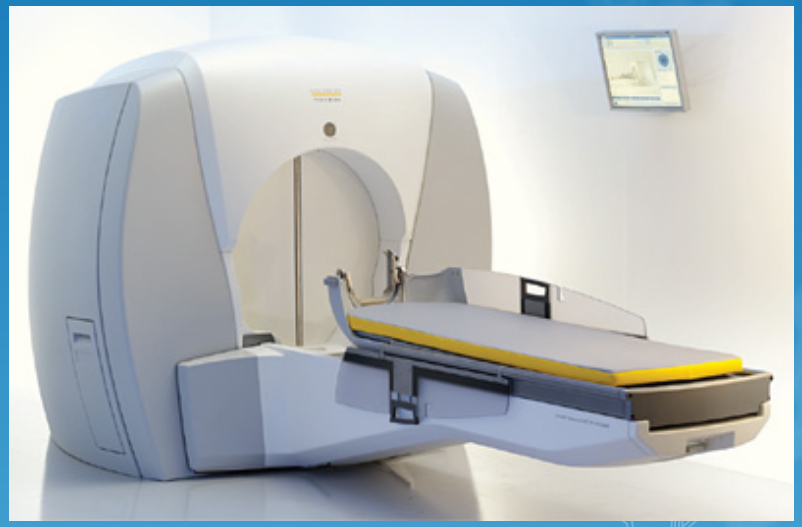


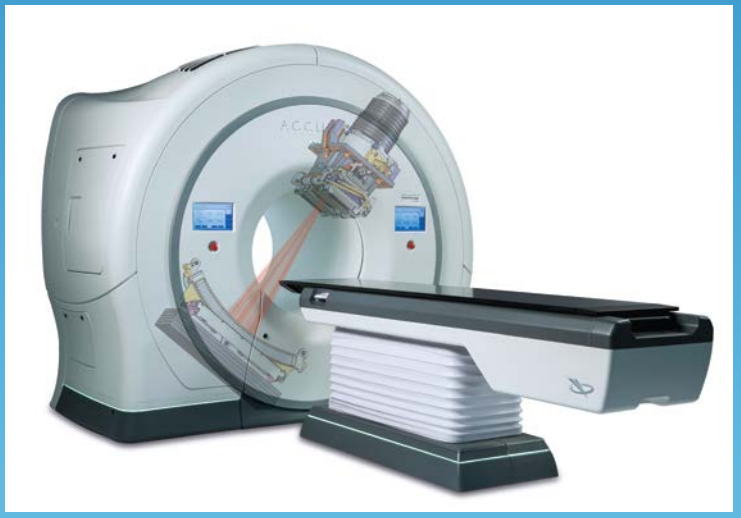
Example: UCD LDR



		Status	Dictated By	Approved...	Approval Date
		Approved	Valicenti, ...	Valicenti, ...	11/19/2015
		Approved	Valicenti, ...	Valicenti, ...	11/23/2015
		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			
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/Old 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”





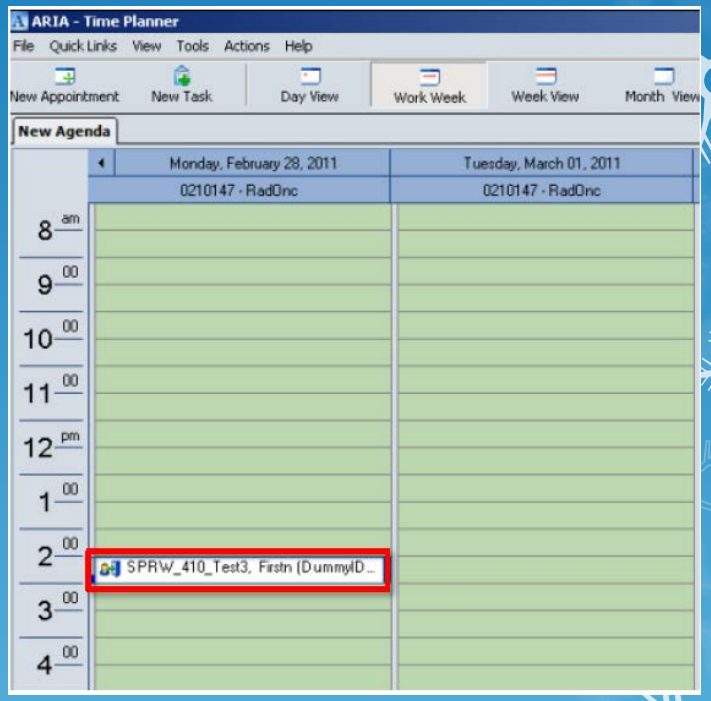
Typical Connectivity Functions (Mileage may vary)

- Scheduling
- Patient demographics
- Total delivered MU

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

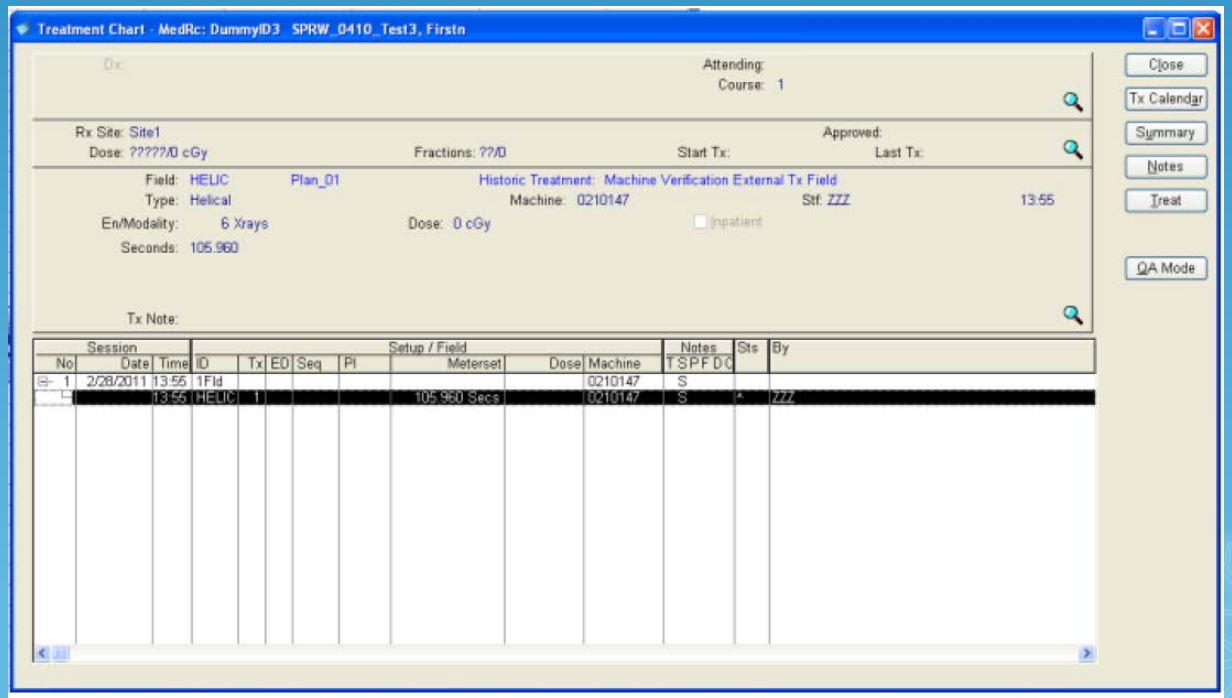
Connectivity Workflow: ARIA

- 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



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



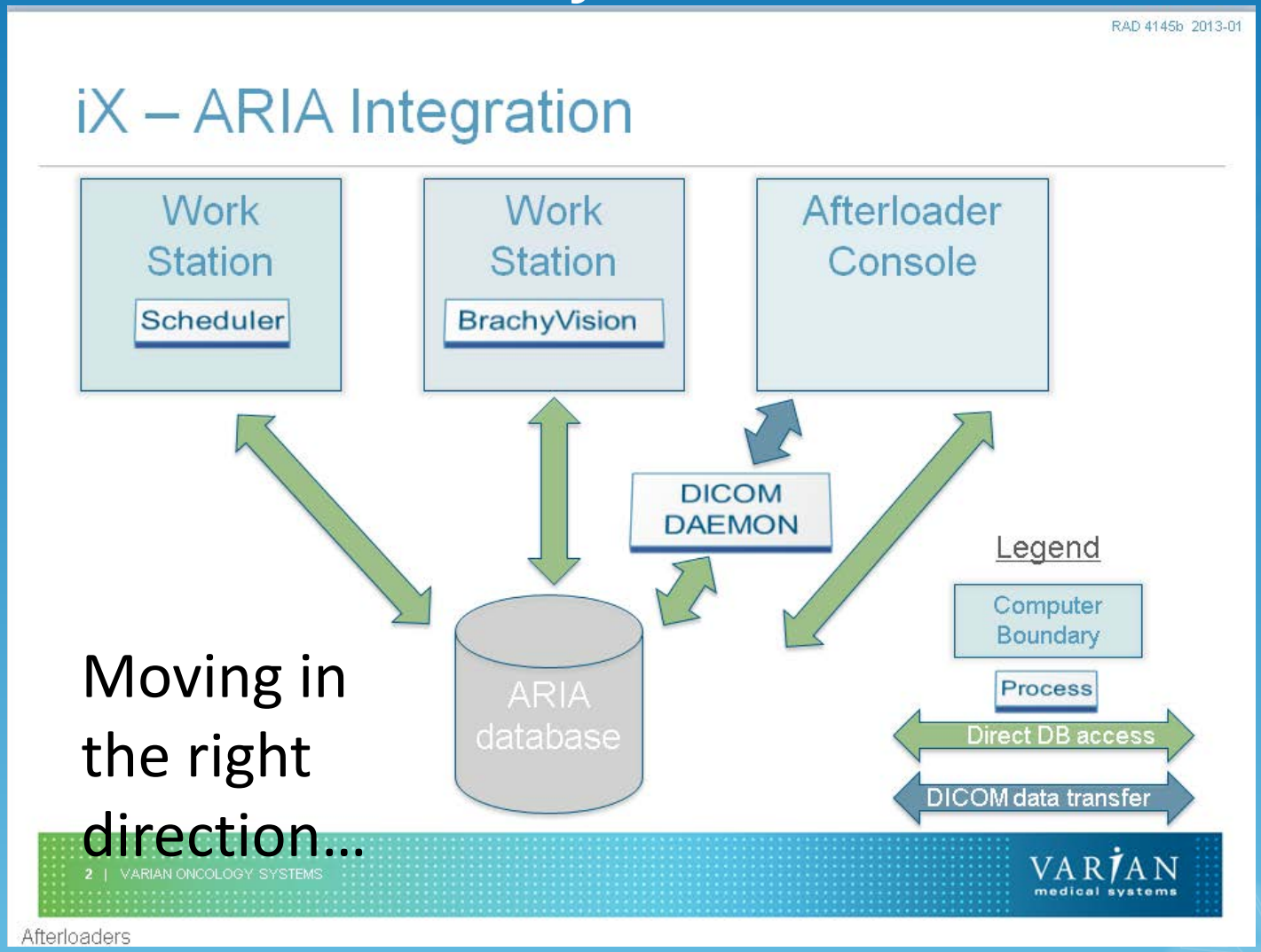
There is always a caveat …

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® and ARIA® 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.

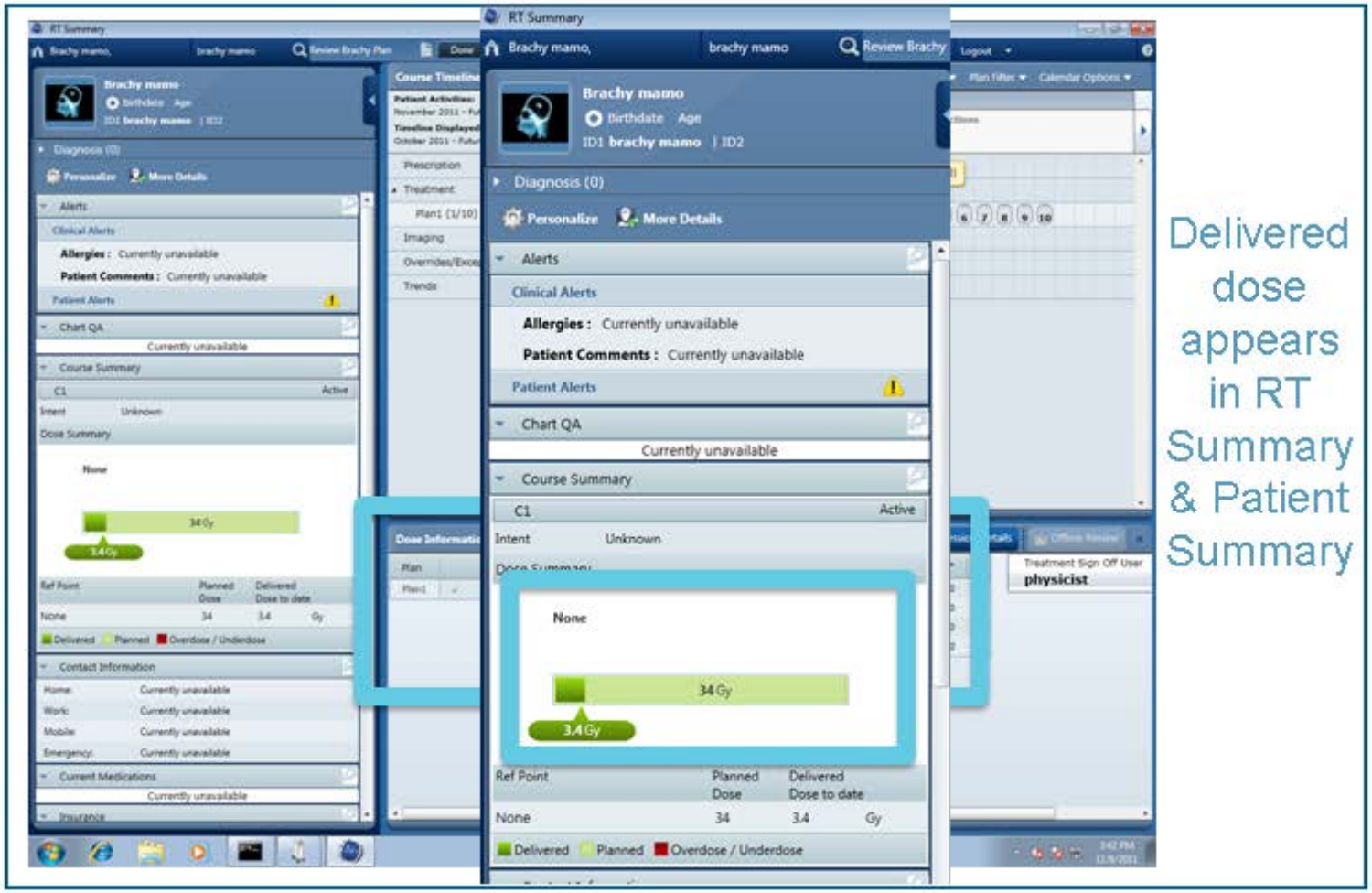
- Good example of keeping customer informed
- Get list of existing tools before making purchase decision
- Each clinic has to design best workaround workflow depending on your documentation needs
- Encourage vendors to participate in IHE-RO connectathons!

Full Connectivity: ARIA/Varisource iX



Courtesy S. Richardson

Brachy HDR Workflow



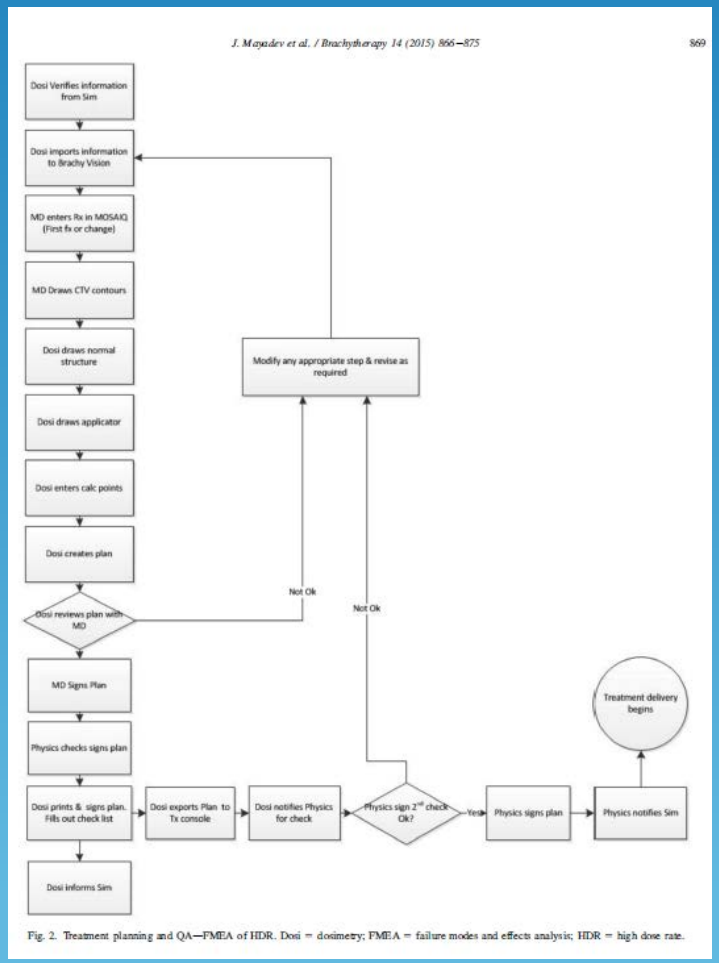
Delivered dose appears in RT Summary & Patient Summary

VARIAN medical systems

Safe use of EMR for Brachy/Similar Devices

Workflow

1. Have one!



2. Document it!

Workflow Alternatives

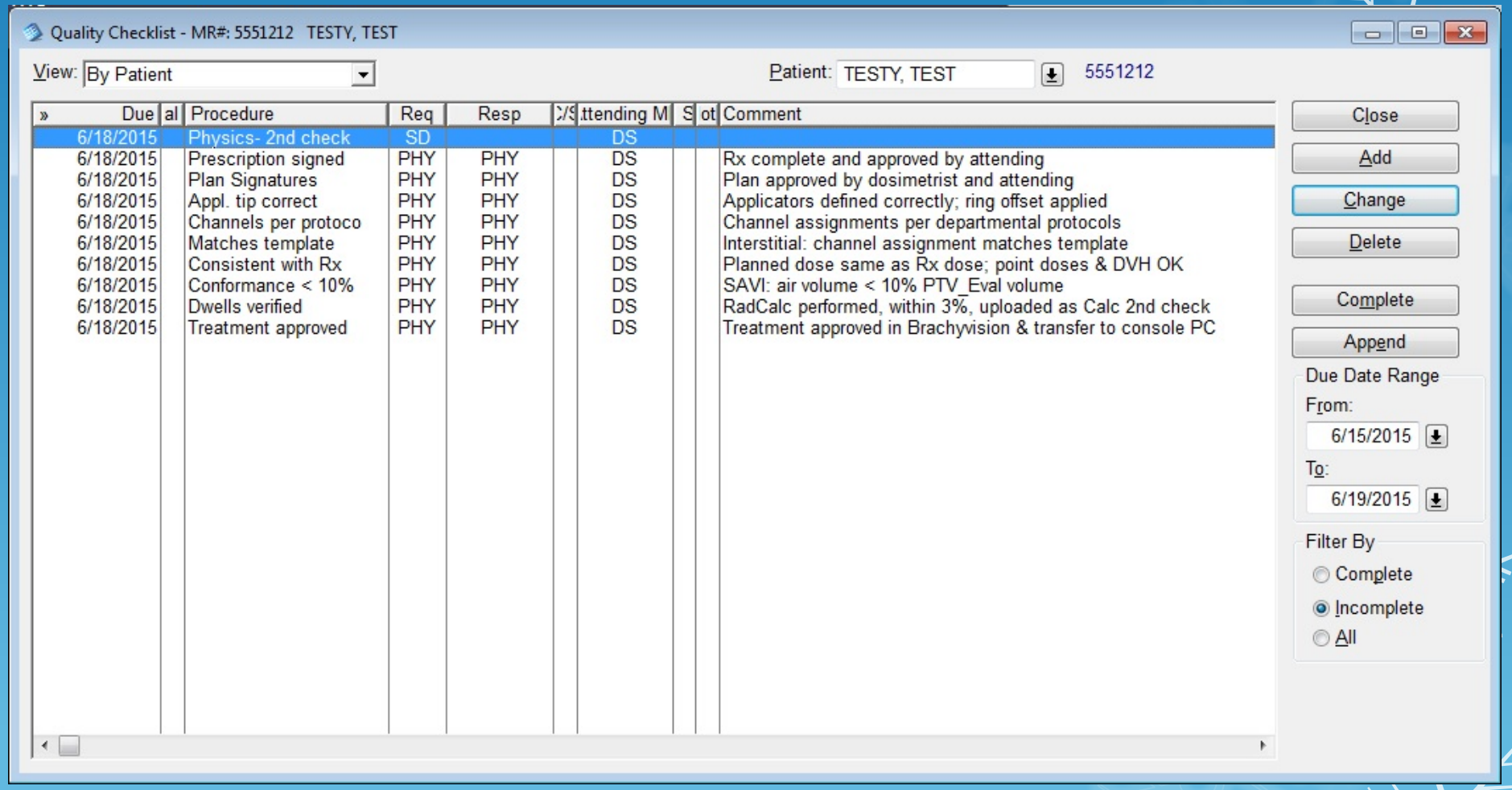
- Network down
- XRT:
  - treat from a local file OR
  - send (some) patients home
- Brachy/Other devices:
  - Plan transfer from TPS to machine via USB/sneakernet
  - Manually enter brachy plan on console from TPS printout
  - Both procedures need to be *commissioned & documented*

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



Safeguard:
Using Checklist Document in ARIA

Patient Name: Date:

MRN: Site/Technique:

MD: Nurse:

Patient Identification: Fraction # of

Treatment Planning Checks:

Mosaiq Written directive is signed and dated by authorized user:

Brachyvision Treatment plan- number of catheters and lengths correct:

Brachyvision Treatment plan dose matches written directive prescription:

MU check performed if treating from non-standard plan:

Pre-Treatment checks

Daily QA performed:

Brachyvision Treatment plan transferred to GammaMed afterloader correctly:

Patient was connected to afterloader and checked by 2 individuals:

Calculated treatment time matches afterloader:

= Decay Factor x treatment planning time = Total Time

= x = 0

GammaMed wheels locked:

Treatment plan approved in Mosaiq by authorized user:

Safeguard:
Using Questionnaire in ARIA

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

1st Day of Treatment

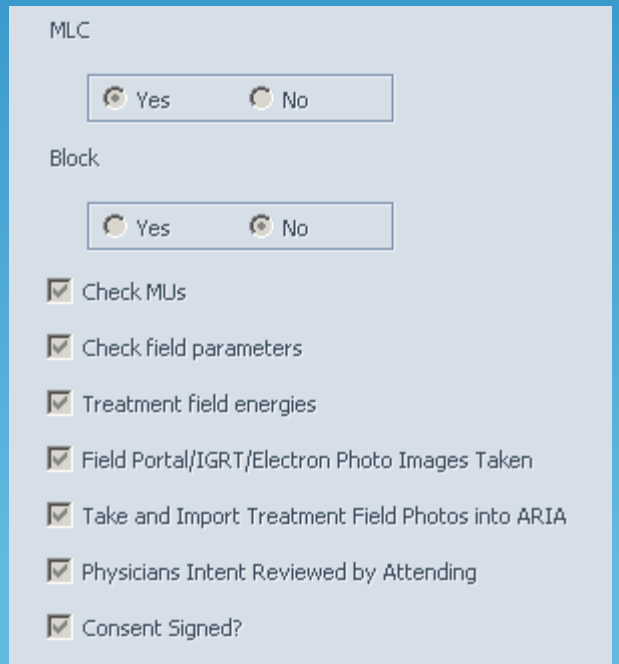
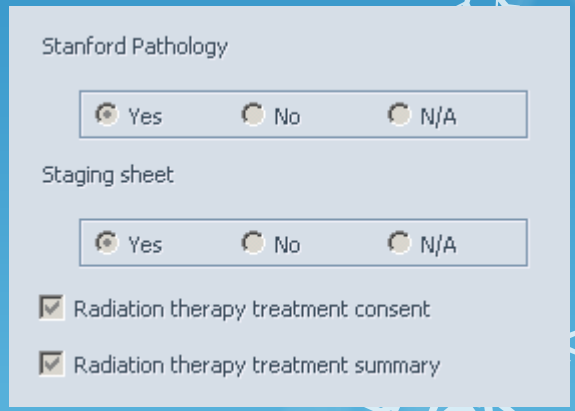


Chart Rounds



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 ***and to ensure that the right information is passed between various system components and systems****."*
- 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, https://vimeo.com/90160027
- Accuray Training department for screen captures from ARIA