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NRC Medical Webinar Training: Brachytherapy Medical Event Reporting

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Outline

- Brachytherapy Medical Events Overview
- High Dose Rate
  - Overview
  - Recent Medical Events
- Yttrium-90 Microspheres
  - Overview
  - Guidance Updates
  - Recent Medical Events

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Disclaimer

- This presentation is based on current regulations in 10 CFR 35 and Yttrium-90 (Y-90) Microsphere Brachytherapy Licensing Guidance, Revision 9

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BRACHYTHERAPY MEDICAL EVENTS OVERVIEW

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Medical Event Purpose

- The purpose of reporting medical events is to identify their causes in order to correct them and prevent their recurrence.
- Medical events reporting allows for identification of trends and ability to provide information that may prevent similar incidences.

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Written Directives

- Different requirements for different types of brachytherapy as each has different safety concerns
- All written directives (WD) require:
  - AU Signature,
  - Date, and
  - Patient Name

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Written Directive (cont.)

- Y-90 microsphere and HDR covered later
- For all other brachytherapy:
  - Before Implantation:
    - Radionuclide
    - Treatment Site
    - Dose
  - After Implantation but before completion
    - Radionuclide
    - Treatment site
    - Number of sources and total strength
    - Exposure time or total dose

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Written Directives (cont.)

- Revision to existing written directive may be made if revision is dated and signed by AU before administration, or
- Oral revision is possible if a delay in order to provide a written revision would jeopardize patients health

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10 CFR 35.41

- For all brachytherapy procedures, the licensee shall develop, implement, and maintain written procedures to provide high confidence that
  - A patient's or human research subject's identify is verified before each administration; and
  - Each administration is in accordance with the written directive.

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10 CFR 35.41 (cont.)

- For brachytherapy the licensee must, at a minimum:
  - Verify patient identity;
  - Verify that the administration is in accordance with the written directive; and
  - Check both manual and computer-generated dose calculations.

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Performance Based Inspections

- “Have you had any procedures not go as planned?”
- “How do you verify the procedure went in accordance with the written directive”
- Ask the licensee to walk you through their verification process

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Medical Event Criteria 1

- A dose that differs from the prescribed dose more than
  - 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin;
  - and

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Medical Event Criteria 1 (cont.)

- The total dose delivered differs from the prescribed dose by 20 percent or more;
- The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
- The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

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Medical Event Criteria 2

- A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following-
  - (i) An administration of a wrong radioactive drug containing byproduct material;
  - (ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

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Medical Event Criteria 2 (cont.)

- (iii) An administration of a dose or dosage to the wrong individual or human research subject;
- (iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or
- (v) A leaking sealed source.

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Medical Event Criteria 3

- A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

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Medical Event Criteria 4

- A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

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Example 1

- Prostate Permanent Seed Brachytherapy
- Prescribed 14,500 cGy (rad) to prostate
- Many seeds ended up in the bladder, but were quickly removed via cystoscopy so bladder received minimal dose
- Prostate dose determined to be 10,900 cGy (rad) (75% of the prescribed dose)

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Example 1 (cont.)

- Medical event because dose to an organ was greater than 0.5 Sv (50 rem) and total dose delivered differed from prescribed dose by 20 percent or more

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Example 2

- Prostate Permanent Seed Brachytherapy
- Prescribed 70 I-125 seeds containing 14.8 MBq each (1,036 MBq total) for permanent implant into prostate
- Delivered 70 I-125 seeds (1,036 MBq) to the prostate but the geometry resulted than dose greater than 120% higher than expected

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Example 2 (cont.)

- Medical event because dose to an organ was greater than 0.5 Sv (50 rem) and total dose delivered differed from prescribed dose by 20 percent or more

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Example 2 (cont.)

- NRC interim enforcement policy provides enforcement discretion for:
  - Using total source strength and exposure time for for determining the existence of a treatment site ME
  - failure to report events when a treatment site total dose exceeds 120 percent of the prescribed dose

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Example 3

- Prostate Permanent Seed Brachytherapy
- Prescribed 16,000 cGy to prostate
- Discovered on post CT image that prostate received 13,600 cGy (85% prescribed dose) and surrounding tissue which was expected to receive minimum dose received 15,000 cGy

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Example 3 (cont.)

- A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

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HDR BRACHYTHERAPY

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Written Directives

- HDR written directives require:
  - patients name,
  - the radionuclide,
  - treatment site,
  - dose per fraction,
  - number of fractions, and
  - total dose

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Medical Event

- 10 CFR 35.3045 Criteria
- Common Criteria for HDR
  - A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive

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Medical Event Purpose

- Treatment success dependent on source position
- Many medical events identified due to unexpected side effects
- Wrong treatment location can lead to adverse effects, such as burns, ulcerations, and pain requiring surgical intervention

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HDR Medical Events

- FY15 HDR Medical Event Cause
  - 8 Positioning Problems
    - 5 Wrong Positions
    - 3 Wrong Reference Length Entered
  - 2 Wrong patient plan delivered
  - 1 Deficient treatment plans
  - 2 Machine problems

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HDR Medical Event (cont.)

- Corrective Actions in FY15
  - Personnel training, especially when upgrading or changing treatment units
  - Proper timeouts
  - Verification of applicator placement before, during and after treatment
  - Manufacturer notification

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Medical Event 1 Source Reference Length

- Patient prescribed 700 cGy (rad) for 3 fractions for gynecological treatment
- Patient returned with burns to skin on thighs and labia
- Incorrect source reference length (SRL) entered into Treatment Planning System resulted in treatment 100 mm short of treatment site
- Unintended skin dose estimated to be 4,200 cGy (rad)

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Medical Event 1 (cont.) Source Reference Length

- Medical Event - A dose to the skin exceeded 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive
- Corrective actions:
  - Second person check SRL,
  - updated procedures,
  - Use dummy marker in scans,
  - Posting expected SRL for applicator used

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Medical Event 2 Human/Software Interface

- Patient prescribed a total of 3,400 cGy (rad) to breast tissue 1 cm from cavity over 10 fractions
- Following 8th fraction, licensee discovered they failed to correctly set the "start at" position
- Error caused the source placement to be flipped 180 degrees along the applicator's long axis (i.e., mirror image).

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Medical Event 2 Human/Software Interface

- A portion of the treatment site at the tip end of the applicator did not receive the prescribed dose, and a portion of the treatment site at the connector end of the applicator received a higher-than-prescribed dose
- Skin and muscle near connector end received higher-than prescribed dose

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Medical Event 2 Human/Software Interface

Organ or Tissue	CT Slice #	Dose (cGy)	Dose Delivered (cGy)	Percent Difference
Treatment Site – High-Dose Location	40	4,624 (Prescribed)	26,600	+475%
Skin – High-Dose Location	20	2,880 (Expected)	10,488	+265%
Muscle – High-Dose Location	19	3,024 (Expected)	100,160	+3,212%

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Medical Event 2 Human/Software Interface

- Medical Event - A dose to the skin exceeded 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive
- Medical Event - A dose that differs from the prescribed dose more than 0.5 Sv (50 rem) to an organ or tissue and total dose delivered to treatment site was greater than 20 percent

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Older Versions of Ocentra Software

- Before version 4.5, software default “start at” position is the connector end
- Default position cannot be changed
- Savi applicator reconstruction for breast treatments starts at the non-default tip end
- Authorized Medical physicists (AMP) needs to change “start at” position for reconstruction which start at the non-default tip end

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User-Error

- AMP should know what the treatment planning software "start at" position is for each treatment
- Facilities which have older version of this software should have procedures to
  - Remind the AMP to change "start at" position when necessary
  - Require verification that the "start at" position matches the reconstruction

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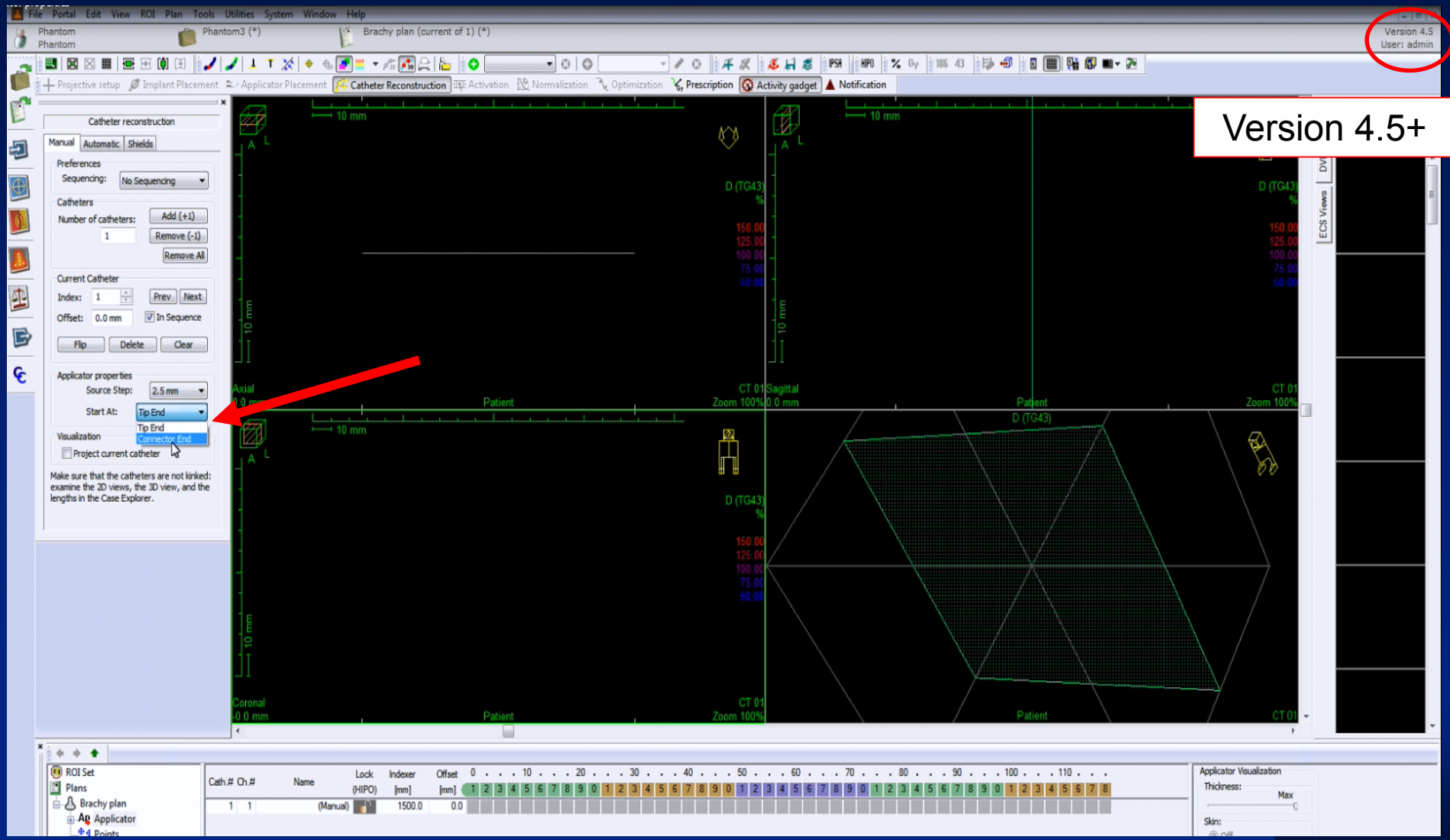
Software Update



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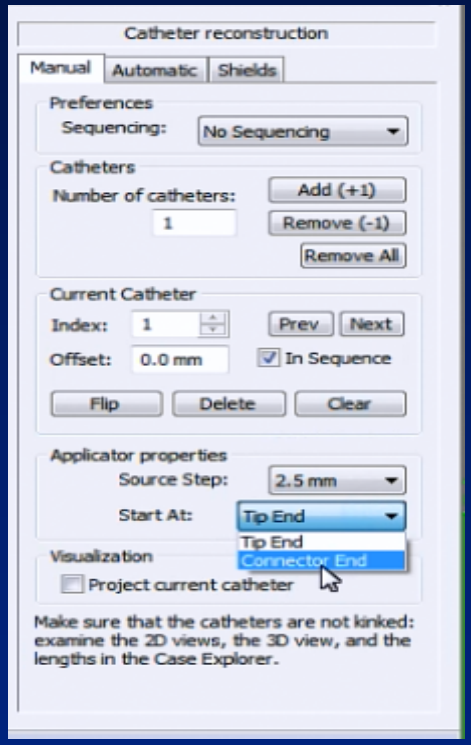
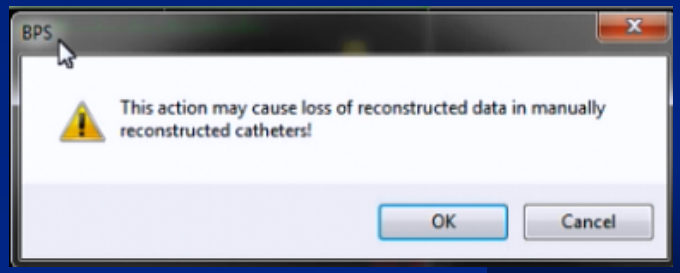
Software Update (cont.)

- User able to change default applicator “Start At” position
- Selected “Start At” position in effect even if treatment plan is not saved
- Warning message appears if change is done after entering manual catheter information





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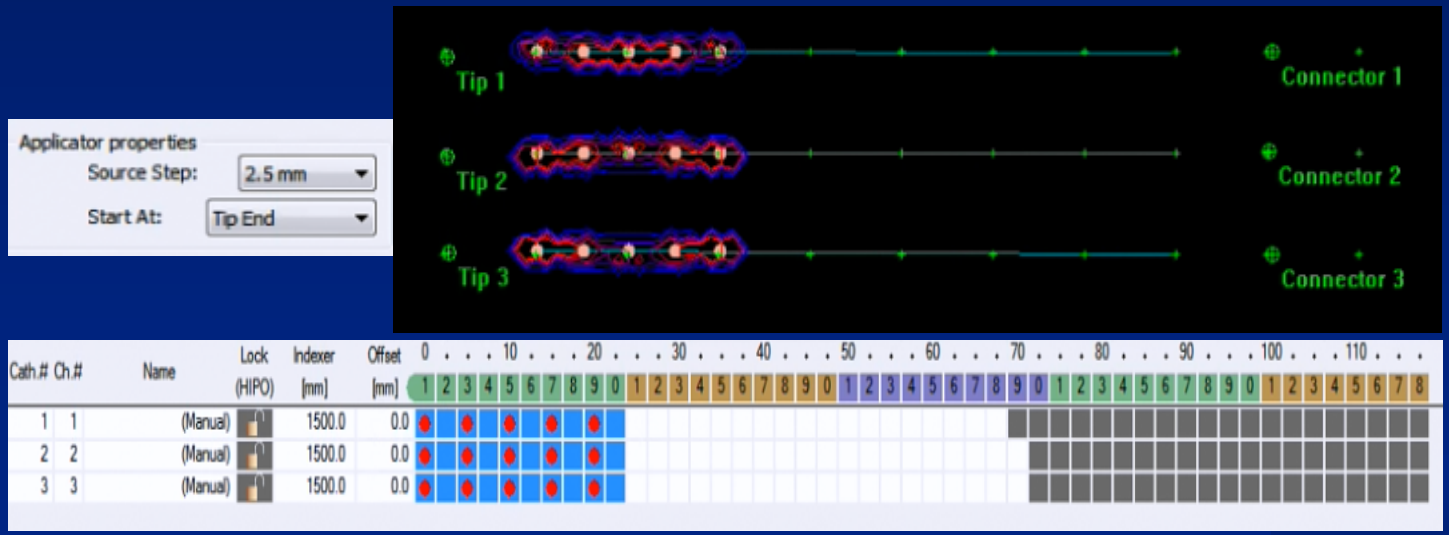
Catheter Reconstruction

- Dose profile is displayed during catheter reconstruction
- Should check offset and dose line up as expected



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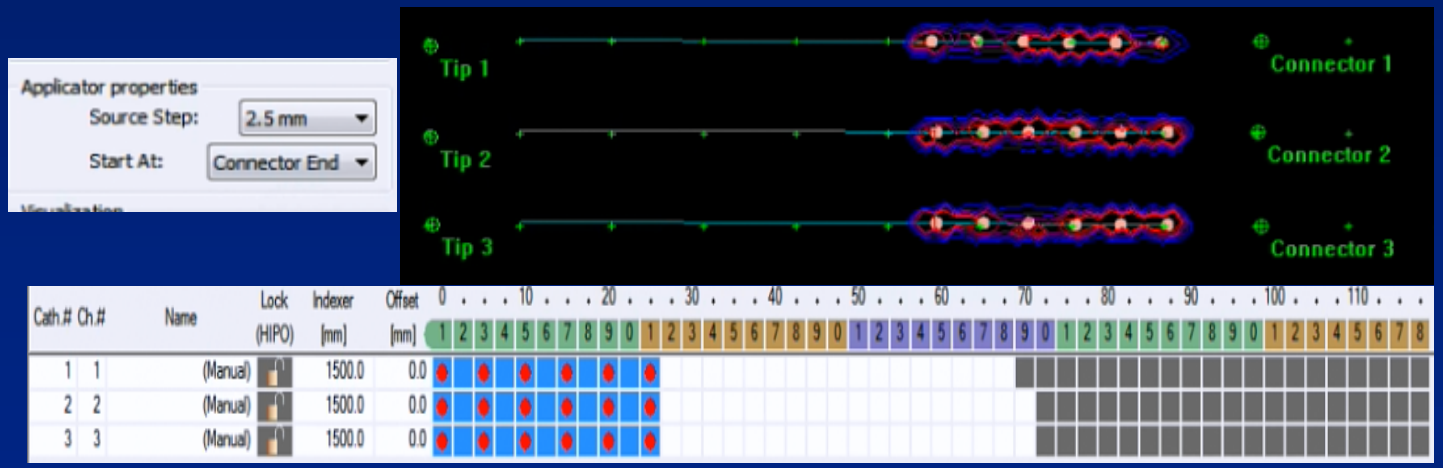
Catheter Reconstruction (cont.)

- Same offset with connector end position will result in new location
- Display shows location of dose in related to the ends



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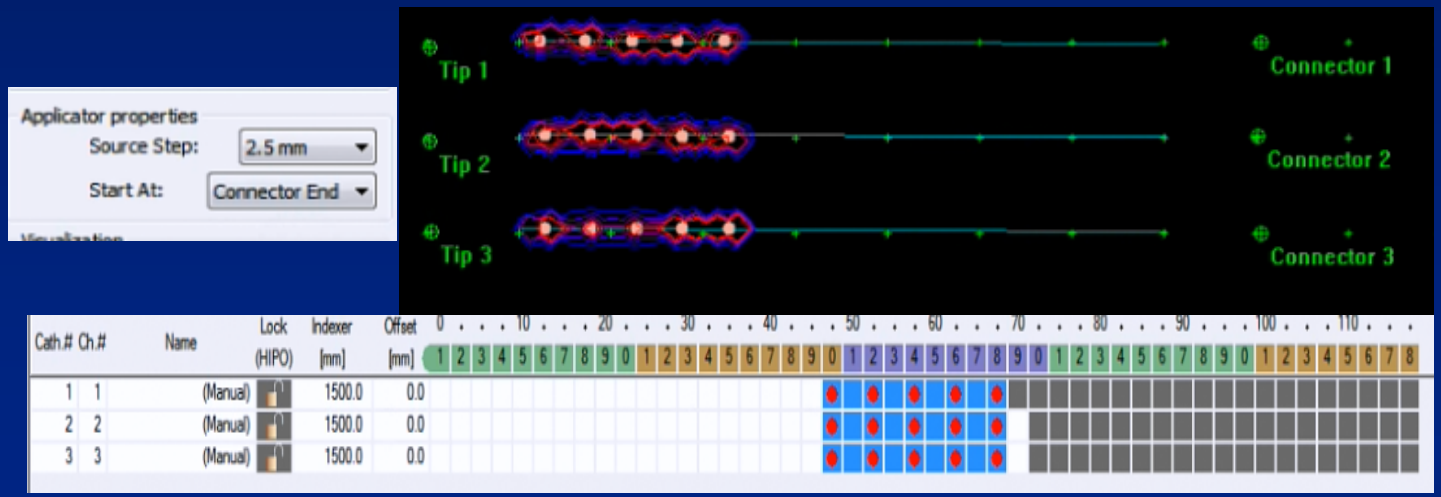
Catheter Reconstruction (cont.)

- Switching start at position requires new offset location



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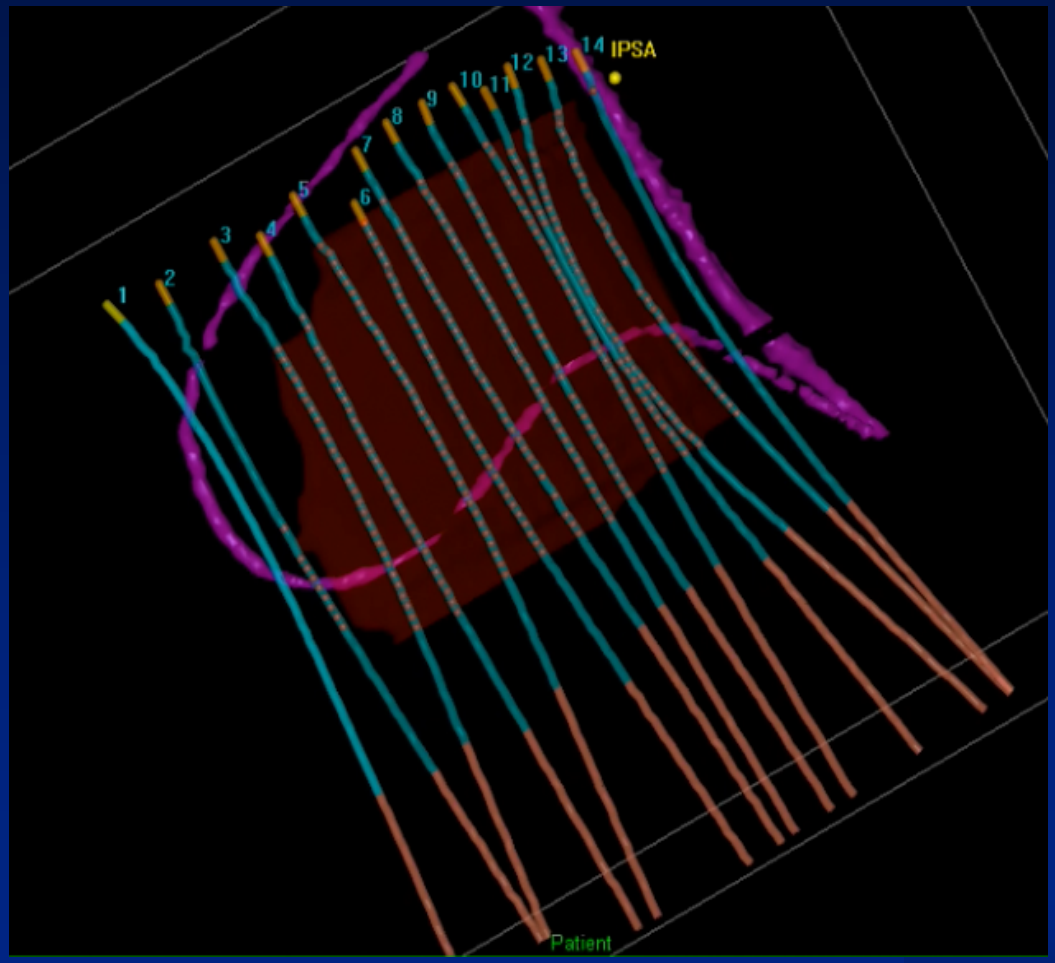
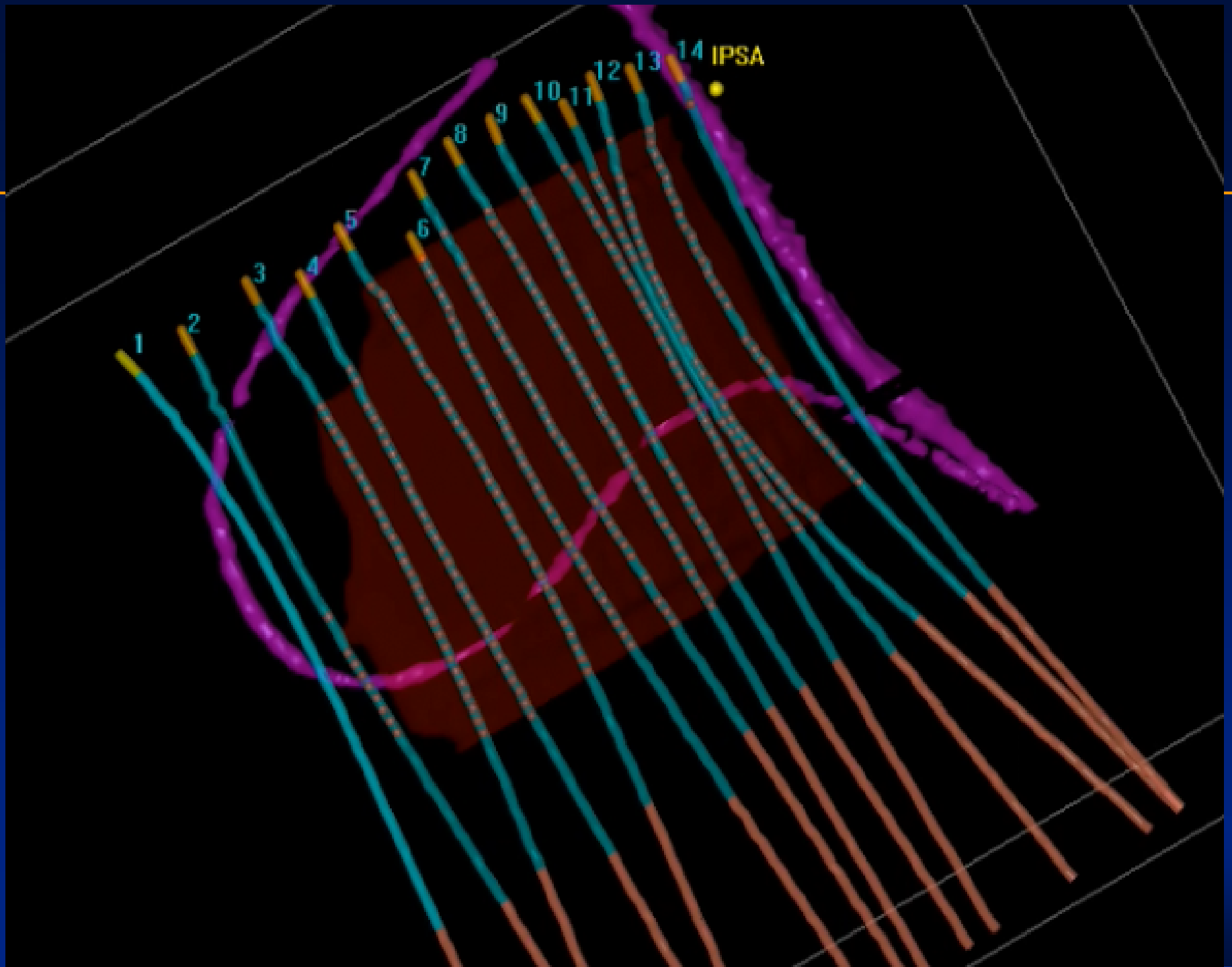
3D Dose Cloud Display

- Tip End – Rounded, numbered & short
- Connector End – Not rounded & long
- Dwell positions shown

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Y-90 MICROSPHERES

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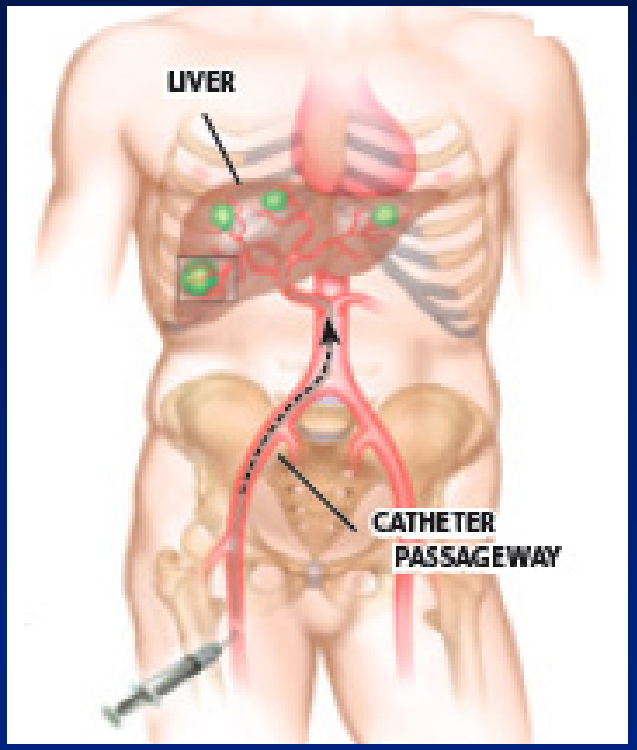
Overview

- Yttrium-90 (Y-90) microspheres treat tumors in the liver
- Goal: Provide localized radiation dose to the tumor volume while sparing normal tissue
  - Dual blood supply
  - Preferential tumor uptake



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Overview (cont.)

- Although considered manual brachytherapy, licensed under 10 CFR 35.1000 because of unique radiation safety characteristics
  - Size and number of microspheres administered
  - Route of administration
- Differences between 2 Manufacturers
  - SIR-Spheres (Resin spheres)
  - TheraSphere (Glass spheres)

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Licensing Guidance Revision

- Revision 9 issued February 12, 2016
- Updated Medical Events definition
  - Excludes reporting events caused by shunting when shunting is evaluated prior to treatment
  - Clarifies that under dose caused by stasis in not a medical event
- Acknowledges American Osteopathic Board of Radiology Vasculature and Interventional Radiologist Certification

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Written Directive

- The written directive shall include
  - the patient or human research subject's name;
  - the date;
  - the signature of an AU for Y-90 microspheres;
  - the treatment site;
  - the radionuclide (including the physical form [Y-90 microspheres]);
  - the manufacturer;

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Written Directive (cont.)

- The written directive shall include (cont.)
  - the prescribed dose or activity;
  - and, if appropriate for the type of microsphere used, the statement “or dose or activity delivered at stasis.”
- Stasis
  - Interventional Radiologist can see stasis during angiogram

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Written Directive

- For Y-90 microsphere brachytherapy, prescribed activity may be used in lieu of prescribed dose.
- If prescribed activity is used, activity should be used for all documentation and evaluations.

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Y-90 Medical Event

- The administration that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or
- The administration of byproduct material: to the wrong individual or human research subject; via the wrong route; or by the wrong mode of treatment; or

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Y-90 Medical Event (cont.)

- The total dose or activity administered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when the following cause is documented:
  - Stasis, or
  - Emergent patient conditions

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Y-90 Medical Event (cont.)

- The administration of byproduct material results in dose or activity to an organ or tissue other than the treatment site, as documented in the written directive, except for shunting when shunting was **evaluated** prior to the treatment in accordance with the manufacturer's procedures

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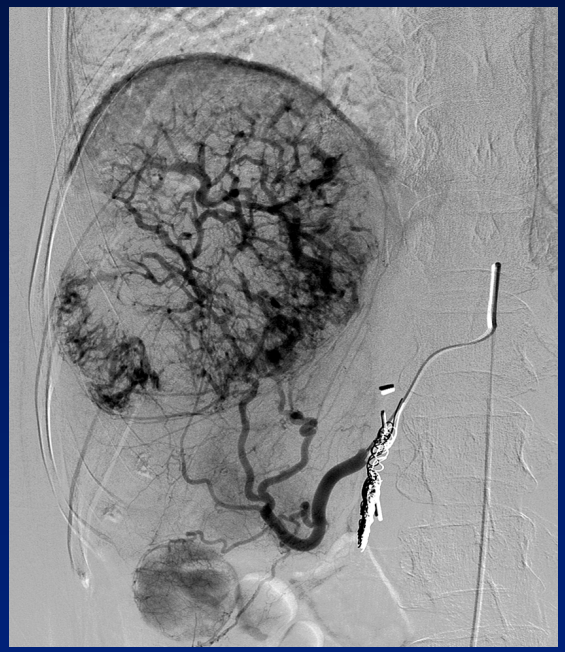
Y90 Typical Workflow

- Patient Selection
- Planning Angiogram
- Lung Shunt Evaluation (SPECT)
- ^{90}Y Radioembolization
- Follow-up



Angiogram

^{99m}Tc – MAA SPECT

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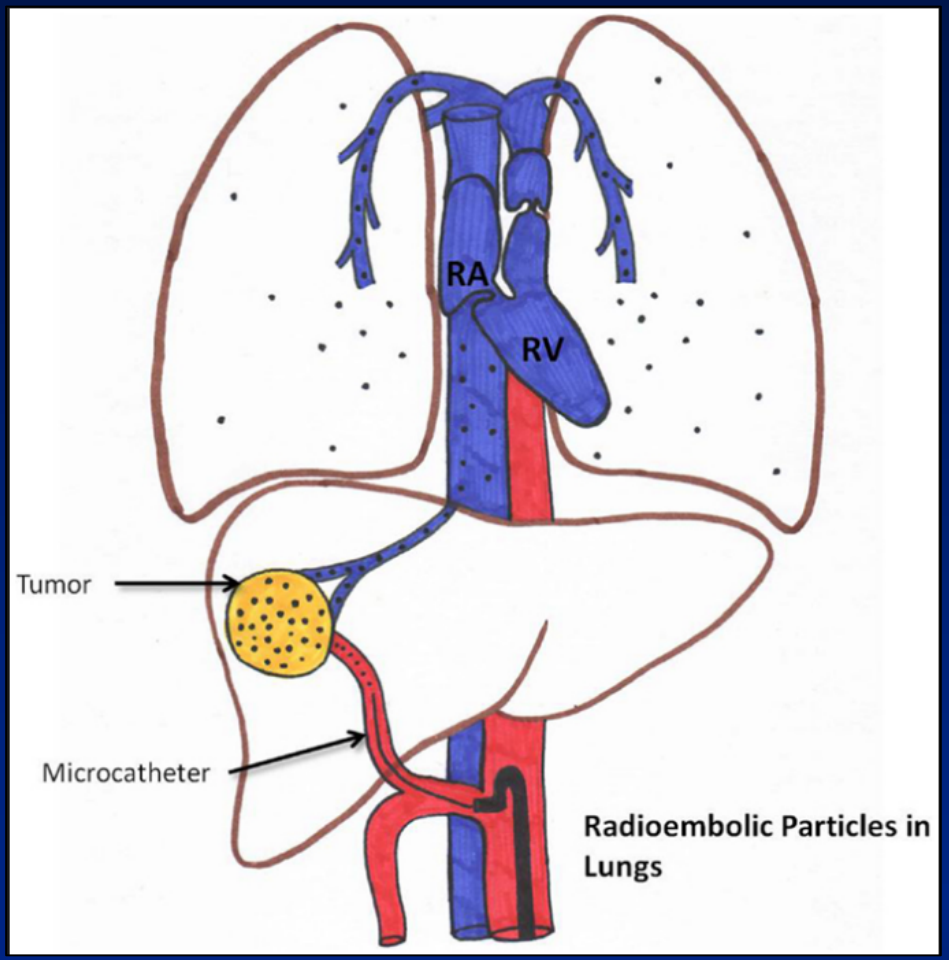
Shunting

- Definition: To move body fluid from one place to another
- Common Locations
  - Lung and Gastrointestinal (GI) Tract



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Evaluation of Lung Shunting

- Technetcium – 99m MAA used as a Y-90 surrogate approximately 2 weeks prior to treatment
- Amount of lung shunting is described as a lung shunt fraction (LSF)
- LSF is determined by ratio of gamma emission count in the lungs to total count in lungs and liver

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Evaluation of Lung Shunting (cont.)

- Radiation pneumonitis and irreversible lung edema and fibrosis has been observed due to lung shunting
- AUs may choose to treat if LSF is expected to be above manufacturer recommended limits as that is a practice of medicine decision

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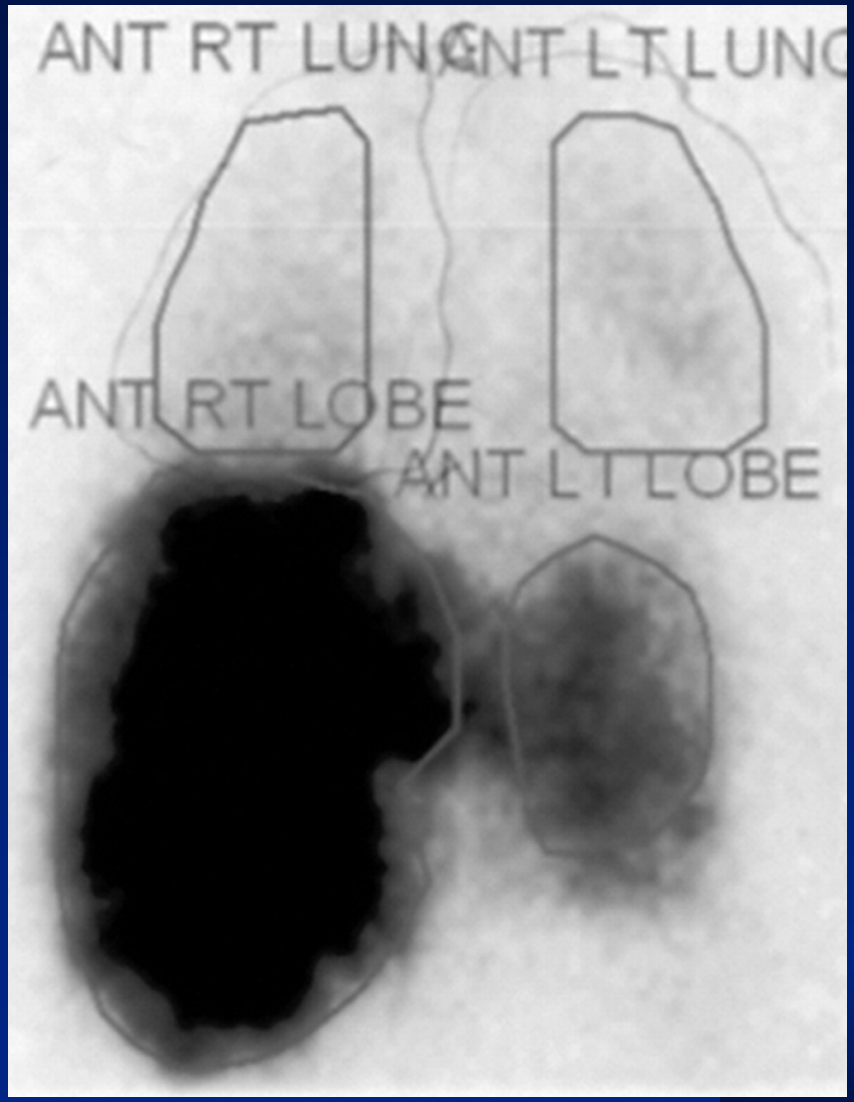
Evaluation of Lung Shunting (cont.)

- Imaging: Gamma camera (i.e. SPECT or planar scintigraphy)
- Region of Interest drawn around liver and lungs



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Evaluation of Lung Shunting (cont.)

- LSF = $\frac{Counts\ Lung}{Counts\ Lung + Liver}$

-or-

$$\frac{Counts\ Lung}{Total\ Counts}$$

- Counts determined at discretion of radiologist
- Sometimes geometric mean used to determine counts

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GI Tract shunting

- Angiographic occlusion techniques and use of vasoactive drugs may be completed to reduce risk of GI tract shunting
- However, GI tract deposition is still possible and sometimes cannot be completely prevented

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GI Tract shunting (cont.)

- Can cause GI tract ulceration
- Both manufacturers list known GI tract flow as a contradiction
- AUs may choose to treat if GI tract flow is observed prior to treatment as that is a practice of medicine decision

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Evaluation and Prevention of GI Tract shunting (cont.)

- Technetcium – 99m MAA pre-treatment image should be evaluated
- Pre-assessment angiogram to determine arterial anatomy of liver which is done at the same time as the Tc-99m MAA
- Angiogram is done prior to treatment to ensure catheter location is correct

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Evaluation and Prevention of GI Tract shunting

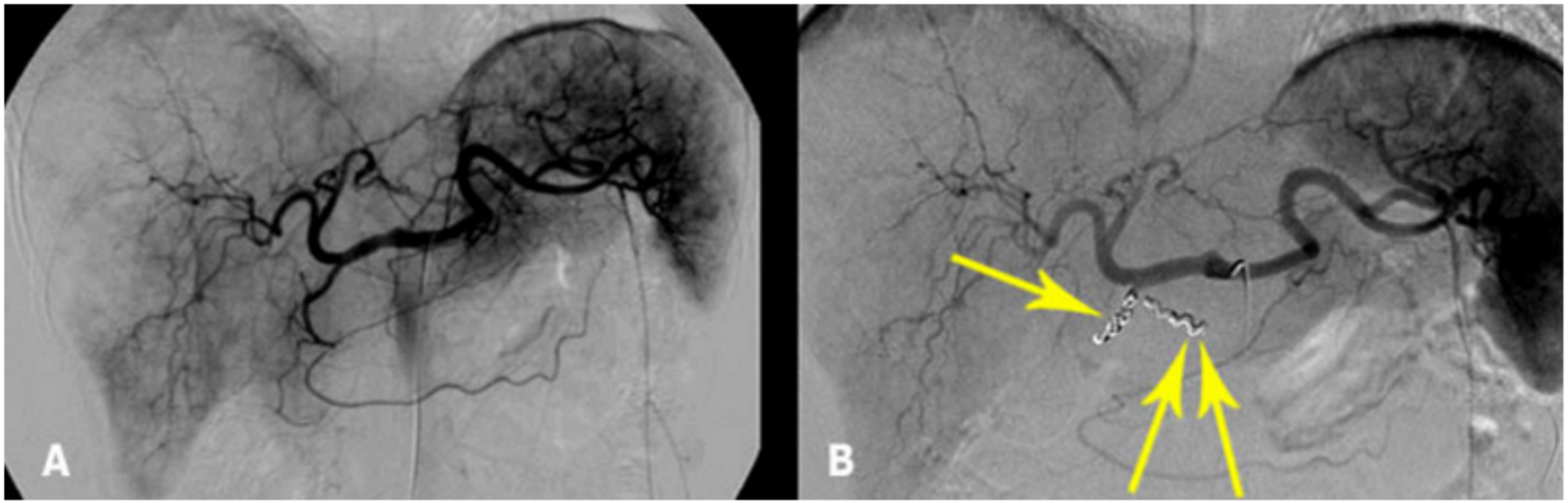

Figure 4. (A) Pre-treatment angiogram shows normal celiac artery. **(B)** Angiogram after coil embolization of the gastroduodenal artery (GDA) (single arrow) and right gastric artery (RGA) (two arrows) shows successful embolization with no flow in to these vessels. This is performed to prevent accidental reflux of SIR-Spheres® from the hepatic artery to the gut vessels.

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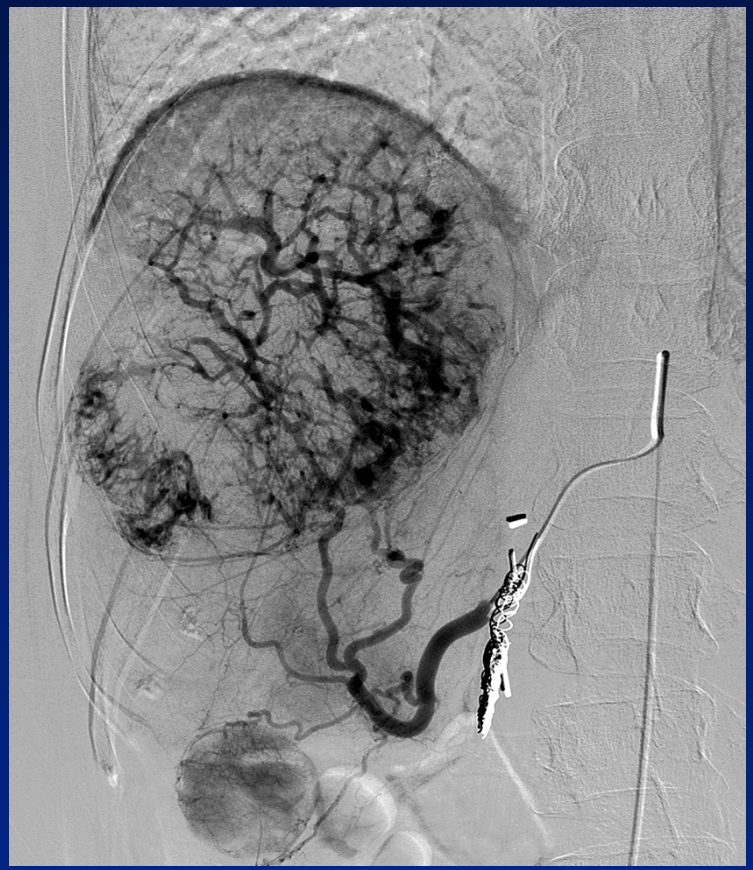
Intrahepatic Shunting

- Liver lesions can cause shunting to occur inside liver
- Should be seen in angiogram prior to administration of Y-90 microspheres
- AU can choose to treat if shunt is observed



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What this Revision Does Not Specify

- This guidance does **not** require an AU to follow manufacturer's procedures to evaluate shunting before treatment
- This guidance does **not** specify the licensee must follow any specific treatment regimen following pre-treatment shunting evaluation
- This guidance does **not except** reporting of medical events caused by incorrect catheter placement

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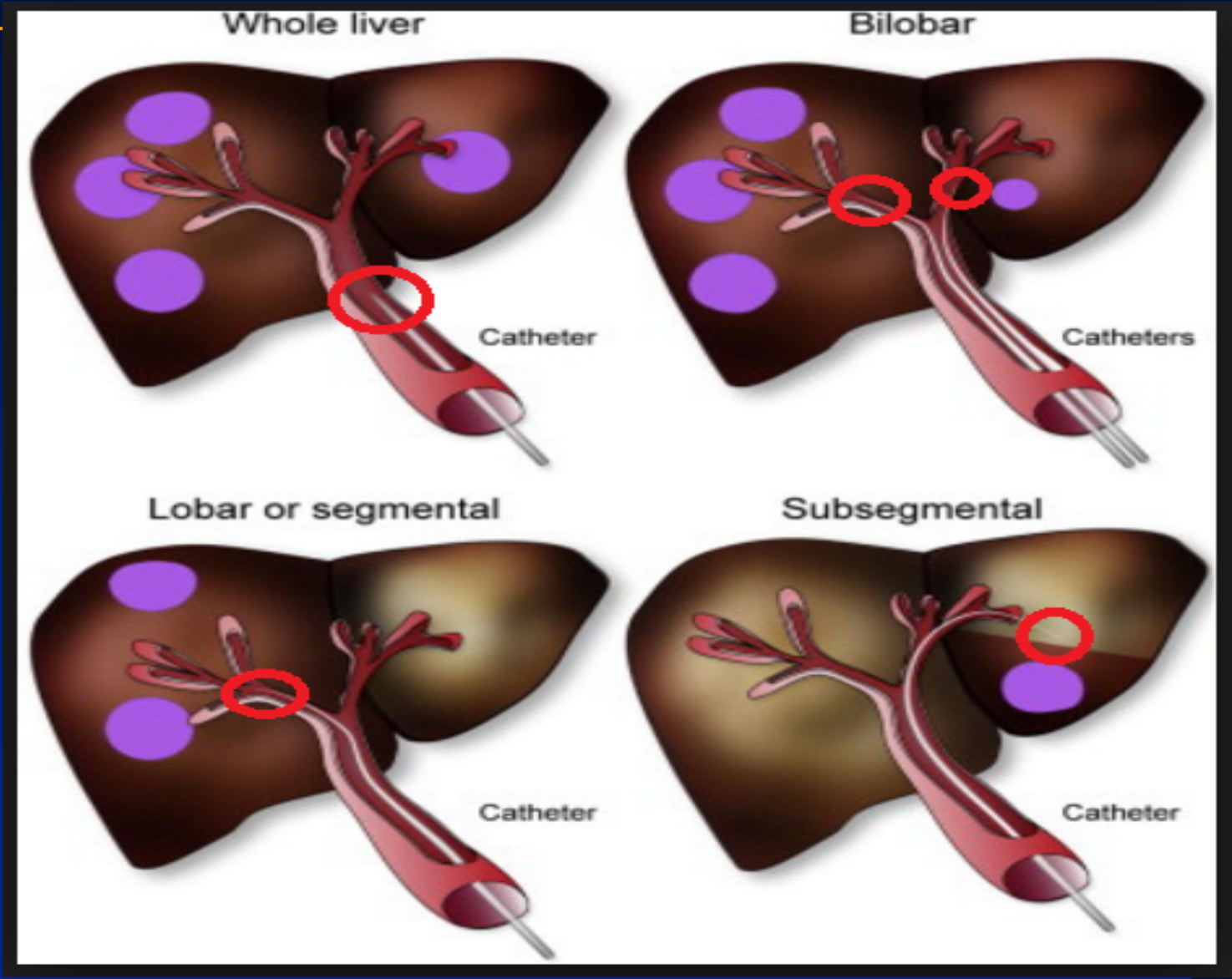
Catheter Position



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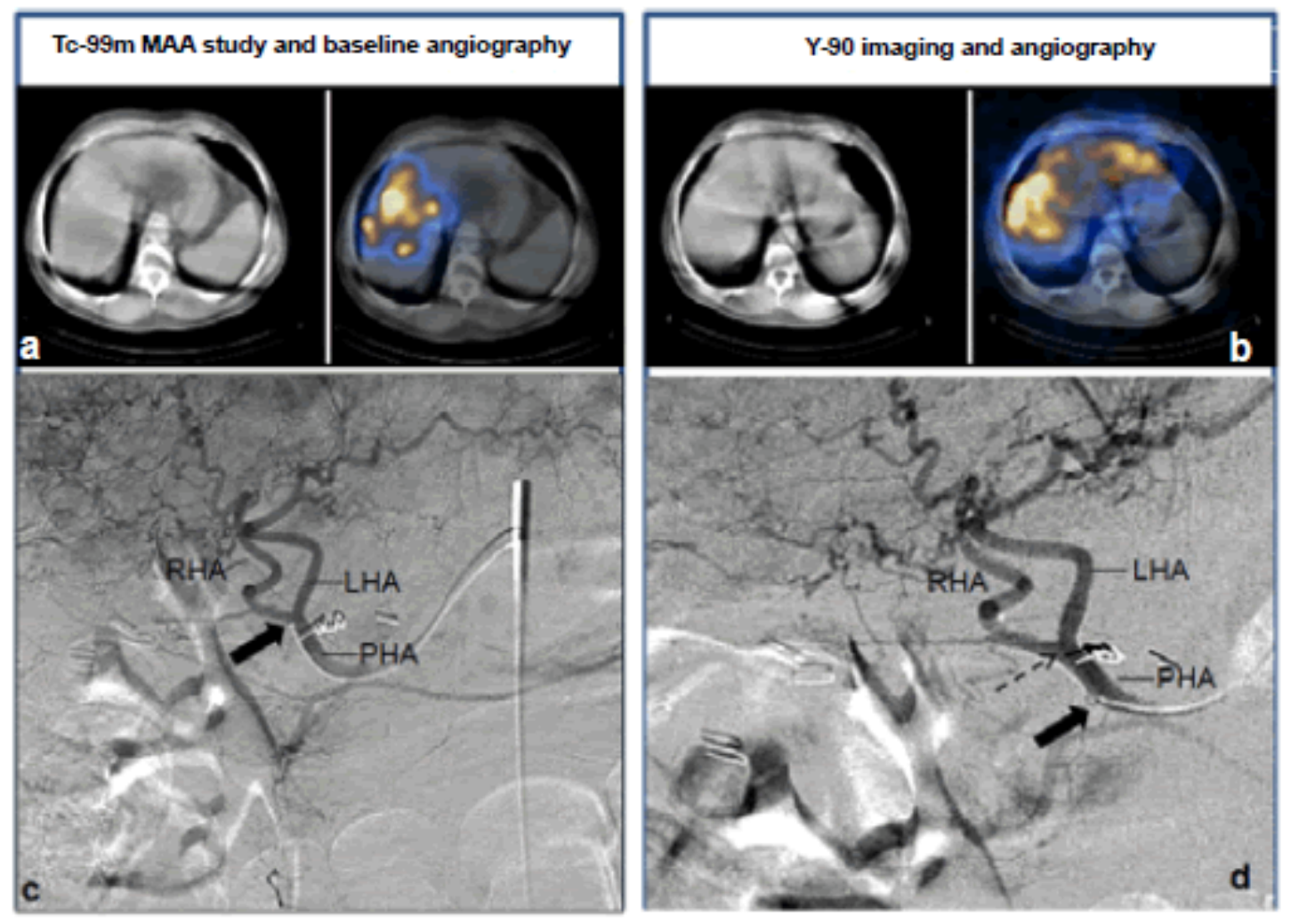
Catheter Placement (cont.)



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10 CFR 35.41

10 CFR 35.41 states, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

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10 CFR 35.41 (cont.)

- In doing this evaluation, we do not require licensees to conduct post-treatment images or use cutting edge medicine.
- Catheter placement should be able to be verified using angiograms and fluoroscopy
- However, if they have information (i.e. post therapy images) which demonstrates a medical event occurred, they need to report the medical event

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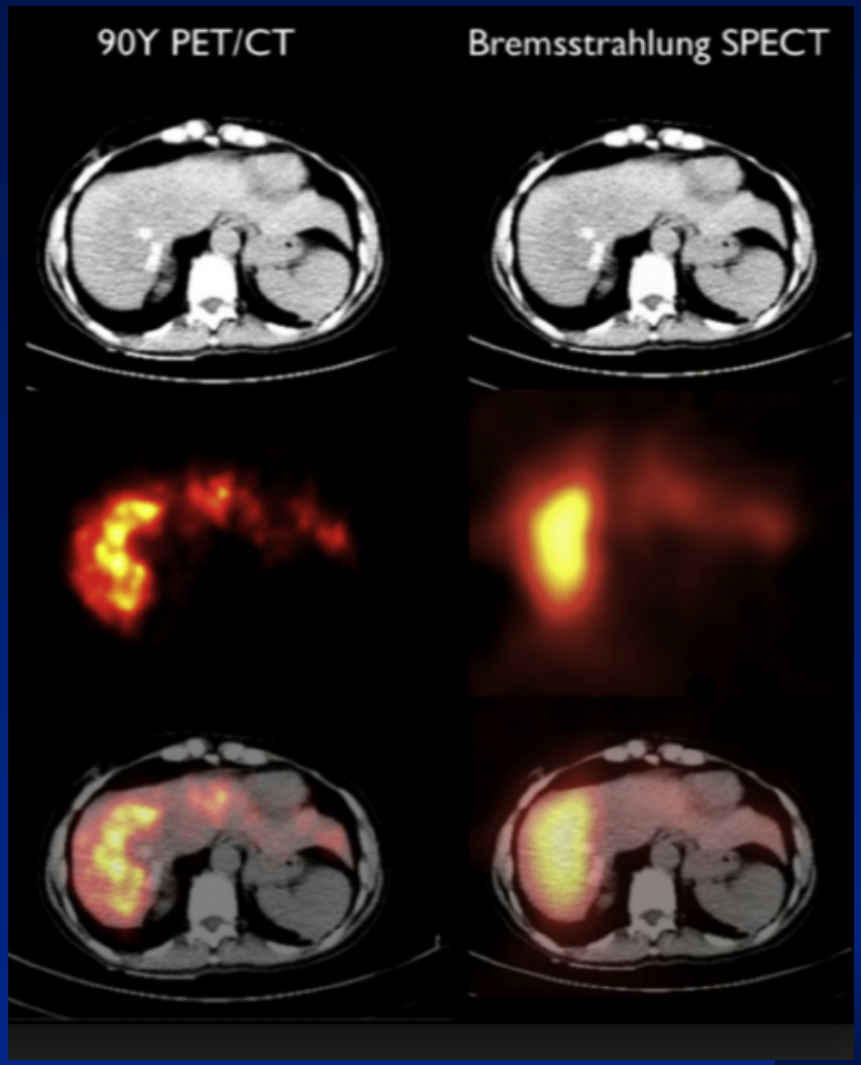
Post Treatment Imaging

- Can show major deviations from written directive
- However,
  - Quantitative Limitations
  - Activity seen outside treatment site may be image artifact



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Medical Event 1

- Written directive: 120 Gy to right lobe
- AU evaluated lung shunt before treatment using Tc-99m MAA procedure, expected 10% of administered dose to go to lungs but discovered on post treatment imaging 30% went to lungs
- Nothing indicated greater than expected lung shunt during treatment.
- Likely not a medical event.

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Medical Event 2

- Written directive: 120 Gy to right lobe
- AU evaluated lung shunt before treatment using Tc-99m MAA procedure, expected 10% of administered dose to go to lungs but discovered on post treatment imaging 30% went to lungs
- After administration, determined wrong patient pretreatment Tc-99m MAA image was evaluated
- Medical Event

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Medical Event 3

- Written directive: 120 Gy to right lobe
- Administration: 80 Gy to left lobe, 40 Gy to right lobe due to suspected catheter movement during delay in delivery
- Medical Event because delivery to wrong treatment site (no exclusion due to shunting)
- Common Corrective Action: Verify catheter placement immediately before administration

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Medical Event 4

- Written directive: 120 Gy to right lobe
- Administered 80 Gy to right lobe, 40 Gy to left lobe
- AU noticed pathway on pre-administration angiogram where contrast was flowing towards left lobe near tumor, but decided to administer Y-90 anyways
- Likely not a medical event as evidence shows shunting likely caused the Y-90 to go to wrong location.

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