# Y90 in the Office-Based Lab

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# Disclosures

- Proctor: Sirtex Medical, Merit Medical
- Consultant: GE, Boston Scientific, Varian

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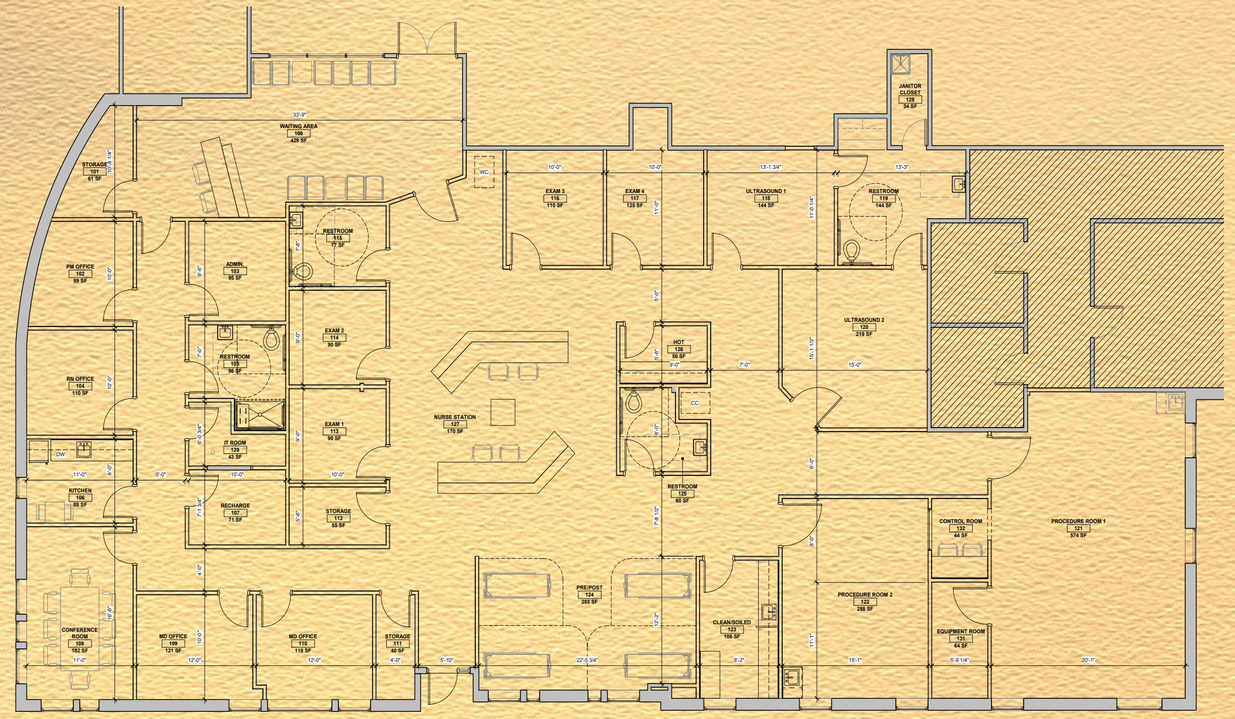
# Hospital Practice of $Y^{90}$

- This is the practice most of us have been exposed to outpatient hospital (POS 22)
- Hospital resources
  - Angiography equipment, supplies and staff, nuclear medicine
  - Infrastructure for handling radioactive materials
  - Coding, billing and scheduling

# Office Based Practice of $Y^{90}$

- Free standing outpatient procedure center (POS11)
- Responsible for all expenses (staff, equipment, $Y^{90}$)
- Understand coding, billing and reimbursement
- Insurance contracts finalized before your 1st treatment
- Business plan to understand risks/benefits of adding $Y^{90}$/MAA to your OBL practice

# BUSINESS PLAN




1 / T1.6 1ST FLOOR PLAN
SCALE 1/4" = 1'-0"

- Lease v Own
- Necessary space
- Fixed Unit v C-arm
- Anticipated # of cases
- Nuclear capabilities
- Local reimbursement

CIO Symposium on Clinical Interventional Oncology
ECCO ENDOVASCULAR CONSULTANTS OF COLORADO

# Yttrium-90 Radioembolization in the OBL

## Yttrium-90 Radioembolization in the Office-Based Lab

Ryan M. Hickey, MD, John M. Maslowski, BS, Eric T. Aaltonen, MD, MPH, Jeremy Cash Horn, MD, Amish Patel, MD, Akhilesh K. Sista, MD, and Jonathan S. Gross, MD

**ABSTRACT**

**Purpose:** To evaluate the feasibility and benefits of performing yttrium-90 radioembolization in an office-based lab (OBL) compared to a hospital setting.

**Materials and Methods:** A radioembolization program was established in March 2019 in an OBL that is managed by the radiology department of a tertiary care center. Mapping and treatment angiograms performed in the OBL from March 2019 through January 2020 were compared to mapping and treatment angiograms performed in the hospital during the same time period.

**Results:** One hundred seventy-six mapping and treatment angiograms were evaluated. There was no difference in the proportion of mapping versus treatment angiograms performed at each site, the proportion of lobar versus selective dose vial administrations, or the mean number of dose vials administered per treatment procedure. Procedure start delays were longer in the hospital than in the OBL (28.6 minutes vs 0.8 minutes; $P < .0001$), particularly for procedures that were not scheduled as the first case of the day (hospital later case delay, 38.8 minutes vs OBL later case delay, 0.5 minutes; $P < .0001$). Procedures performed in the hospital took longer on average than procedures performed in the OBL (2 hours, 1.8 minutes vs 1 hour, 44.4 minutes; $P = .0004$), particularly for procedures that were not scheduled as the first case of the day (hospital later case duration, 2 hours, 7.4 minutes vs OBL later case duration, 1 hour, 43 minutes; $P = .0006$).

**Conclusions:** Establishing a radioembolization program within an OBL is feasible and might provide more efficient procedure scheduling than the hospital setting.

JVIR 2020

# NYU Experience

- 176 treatments
- Procedure delays were longer in the hospital
- Procedures took longer in the hospital
- Feasible, provides efficient scheduling and treatment outside of the hospital

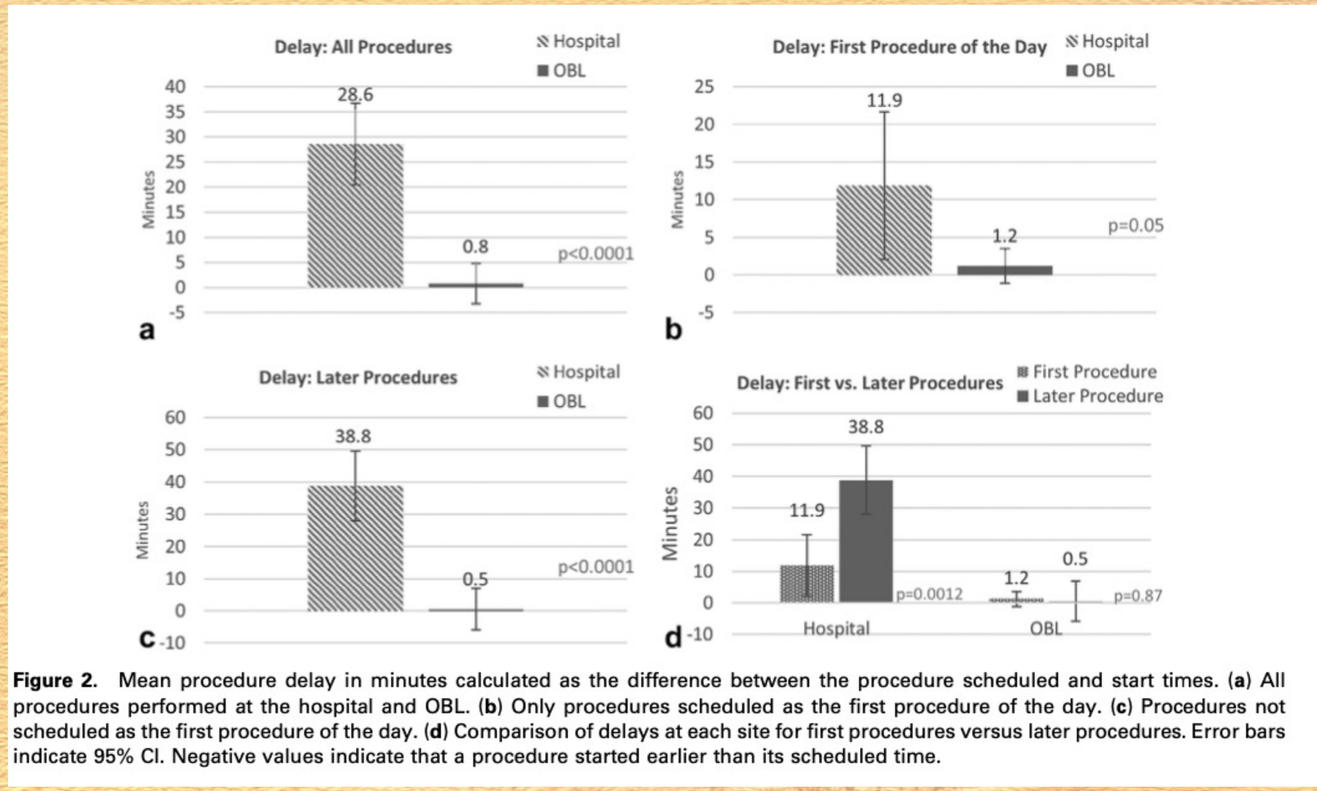



**Figure 2.** Mean procedure delay in minutes calculated as the difference between the procedure scheduled and start times. (**a**) All procedures performed at the hospital and OBL. (**b**) Only procedures scheduled as the first procedure of the day. (**c**) Procedures not scheduled as the first procedure of the day. (**d**) Comparison of delays at each site for first procedures versus later procedures. Error bars indicate 95% CI. Negative values indicate that a procedure started earlier than its scheduled time.

Y90 Radioembolization in the Office-Based Lab, Hickey et al. JVIR 2020

# Payor Authorization and Reimbursement for the OBL

- OBLs are identified as place of service (POS) 11 by CMS
- Negotiated pass through payment for the $Y^{90}$ with commercial insurance prior to treatment
- All patients undergo insurance pre-determination for the MAA and $Y^{90}$ procedures
- HCPCS codes

| HCPCS | Descriptor | Payers | Place of Service (POS) |
|---|---|---|---|
| Q3001 | Radioelements for Brachytherapy, any type | Fee for Service Medicare, some commercial / private payers including Medicare Advantage plans | Office-Based Labs (OBL) 11 |
| S2095 | Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres | some commercial / private payers including Fee for Service Medicare and Medicare Advantage plans | Office-Based Labs (OBL) 11 |
| C2616 | Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres | Not used by Medicare; Used by Blue Cross and Blue Shield and some UHC plans | Office-Based Labs (OBL) 11 |

Y90 Radioembolization in the Office-Based Lab, Hickey et al. JVIR 2020

# Radioactive Material License for Office Based Lab

- Applied for License - Feb 2020
- Virtual State Visit - May 2020
- State Approval - June 2020
- Treated Y90 patient - July 2020
- On site State Visit Q1 - 2021

**NRC FORM 313** U.S. NUCLEAR REGULATORY COMMISSION
(01-2020)
10 CFR 30, 32, 33, 34, 35, 36, 37, 39, and 40

**APPLICATION FOR MATERIALS LICENSE**

**APPROVED BY OMB: NO. 3150-0120** **EXPIRES: 01/31/2023**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

**INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.**

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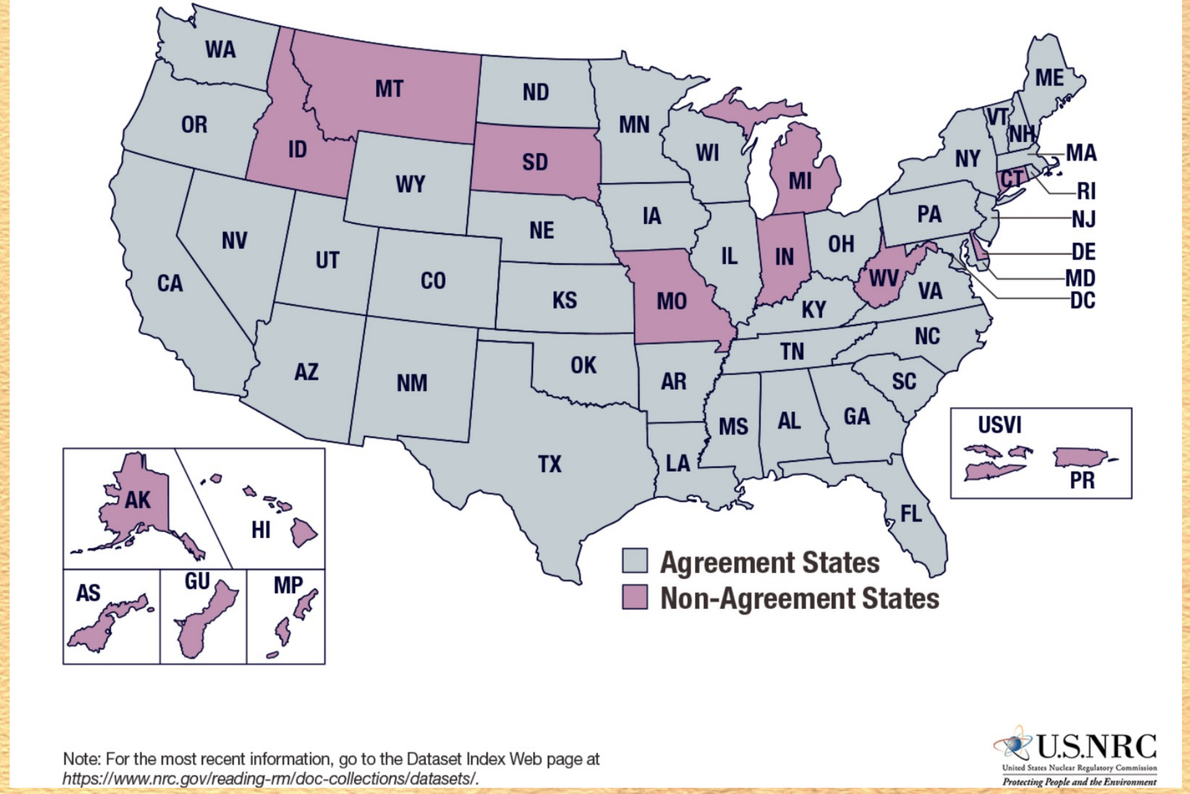
1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - ☐ A. NEW LICENSE
   - ☐ B. AMENDMENT TO LICENSE NUMBER
   - ☐ C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include zip code)*




Note: For the most recent information, go to the Dataset Index Web page at *https://www.nrc.gov/reading-rm/doc-collections/datasets/*.

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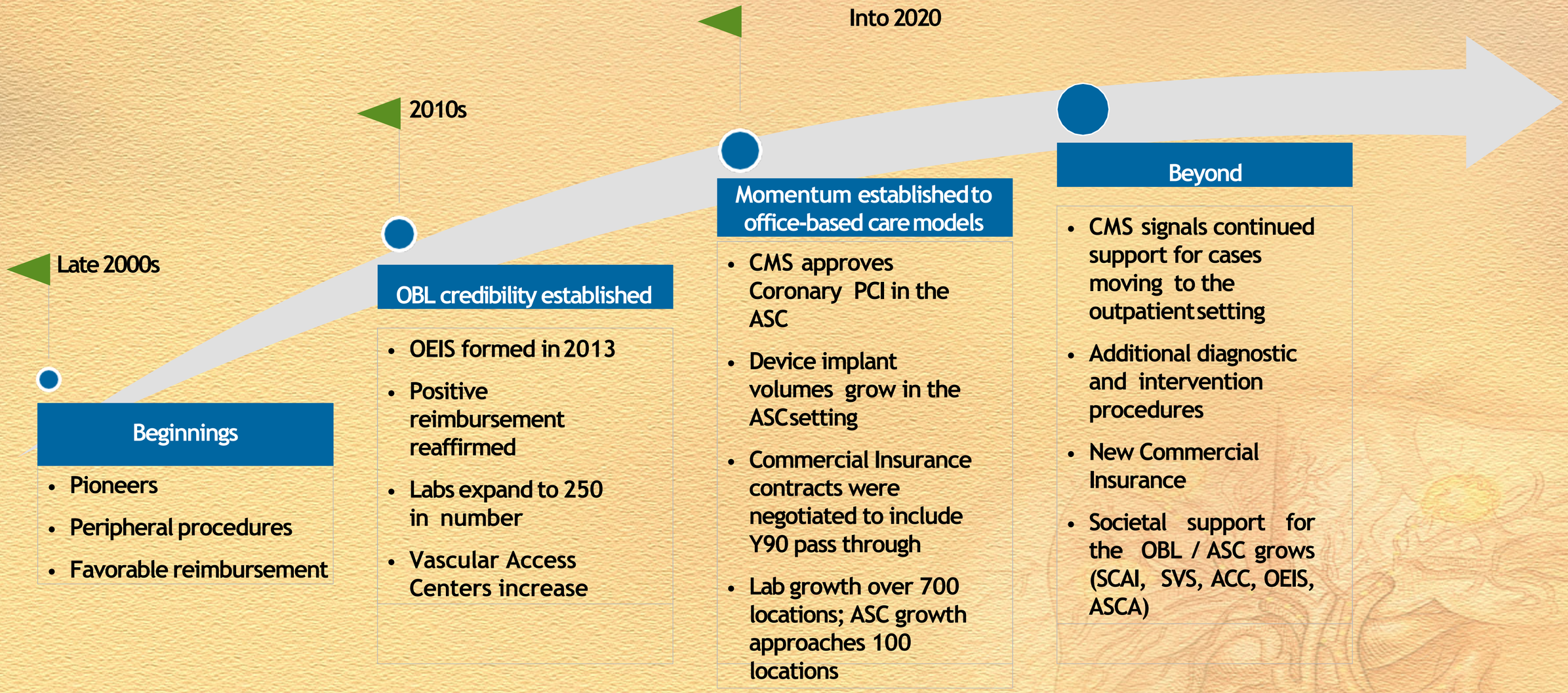
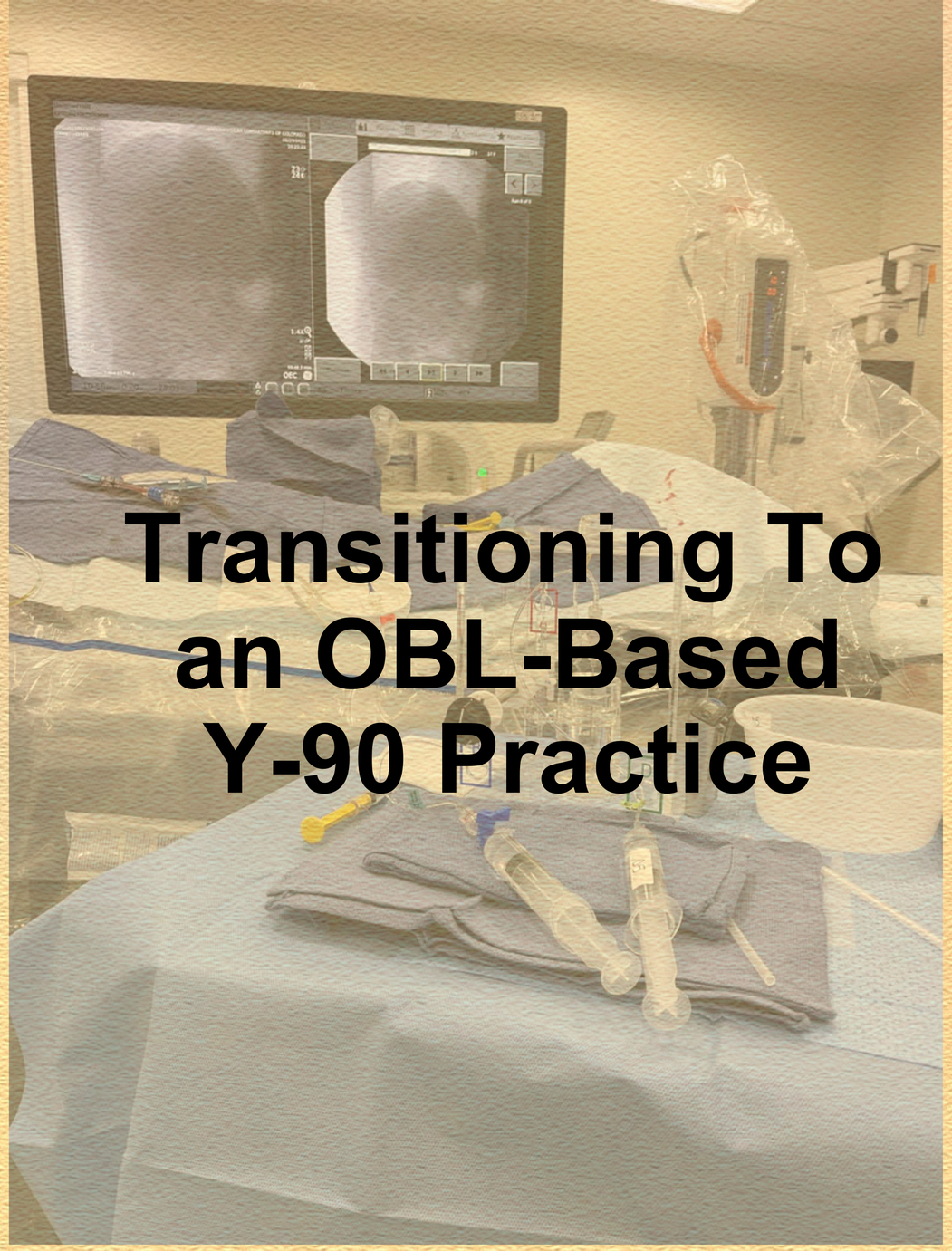
# Evolution of the Office-based lab





# Transitioning To an OBL-Based Y-90 Practice

- Took Advantage of the Industry OBL team to help navigate the transition of our Y-90 program to the OBL
- Applied for our RAML license
  - IR doctors are AU's
  - Utilized a local medical physicist
  - Worked collaboratively with CO state
- Made referrers and patients aware
  - Existing medical, surgical and radiation oncology relationships in place already within our IR team.
  - COVID has made the transition of sending patients to the OBL vs the hospital seamless
- Our patients are referred to our clinic and triaged to Service site 11 (OBL) or 22 (OPH)

# OBL Improves Patient Experience

- Office setting is easier for Y-90 patients to access physically than navigating a hospital.
- Procedure start times are consistent for OBL patients.
- Quicker door to discharge time
- Dedicated nurse follows the patient from start to discharge
- Provides patients with the potential for less risk of infection due to smaller foot traffic at an OBL

# Radioembolization in the Office-Based Lab

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Dig Dis Interv 2021;5:142–147.

**Abstract**

Interventional procedures have been performed on an outpatient basis in the hospital setting for many years, although there has been a clear trend toward performing these procedures in an outpatient facility, such as an ambulatory surgery center or office-based lab. And while this trend initially began with dialysis interventions and then endovascular interventions, interventional oncology is starting to catch on. Radioembolization has routinely been performed in an outpatient setting, and has recently gained traction in office-based labs due to new reimbursement codes, which became available in 2017. This article will outline the safety and feasibility, including economic considerations and demonstrated growth, of performing radioembolization in an office-based lab.

**Keywords**

- office-based lab
- outpatient
- radioembolization

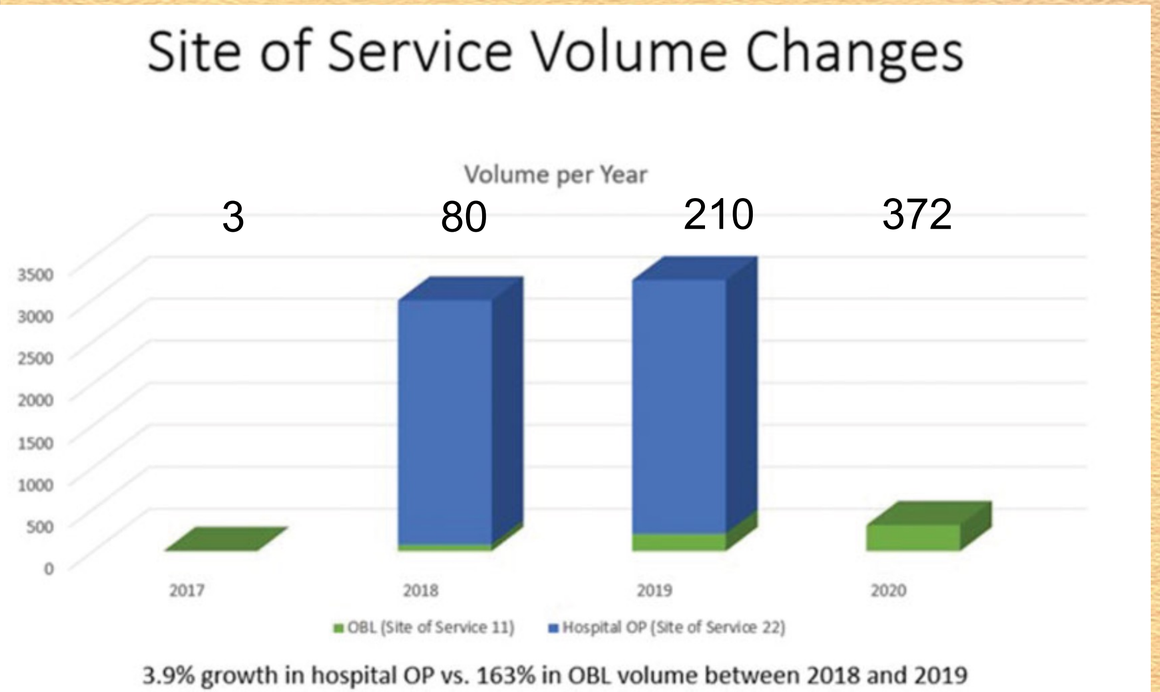



**Fig. 2** Place of service volume changes since reimbursement codes for office-based laboratory (OBL) radioembolization were first introduced.

# Resin SIRT Highlights in OBIS*

- 25 Centers approved with RAM Licenses
- 17 Centers Actively Treating patients.
- 800+ Patients treated in office setting.
- 700+ Patient reimbursements
- Confirmed commercial payments

***As of June 1st, 2021***

*** Provided by Sirtex**

# Mapping and Y90 Treatment Options

Mapping only in the office-based suite?

Treatment only in the office-based suite?

Mapping and Treatment in the office-based suite?

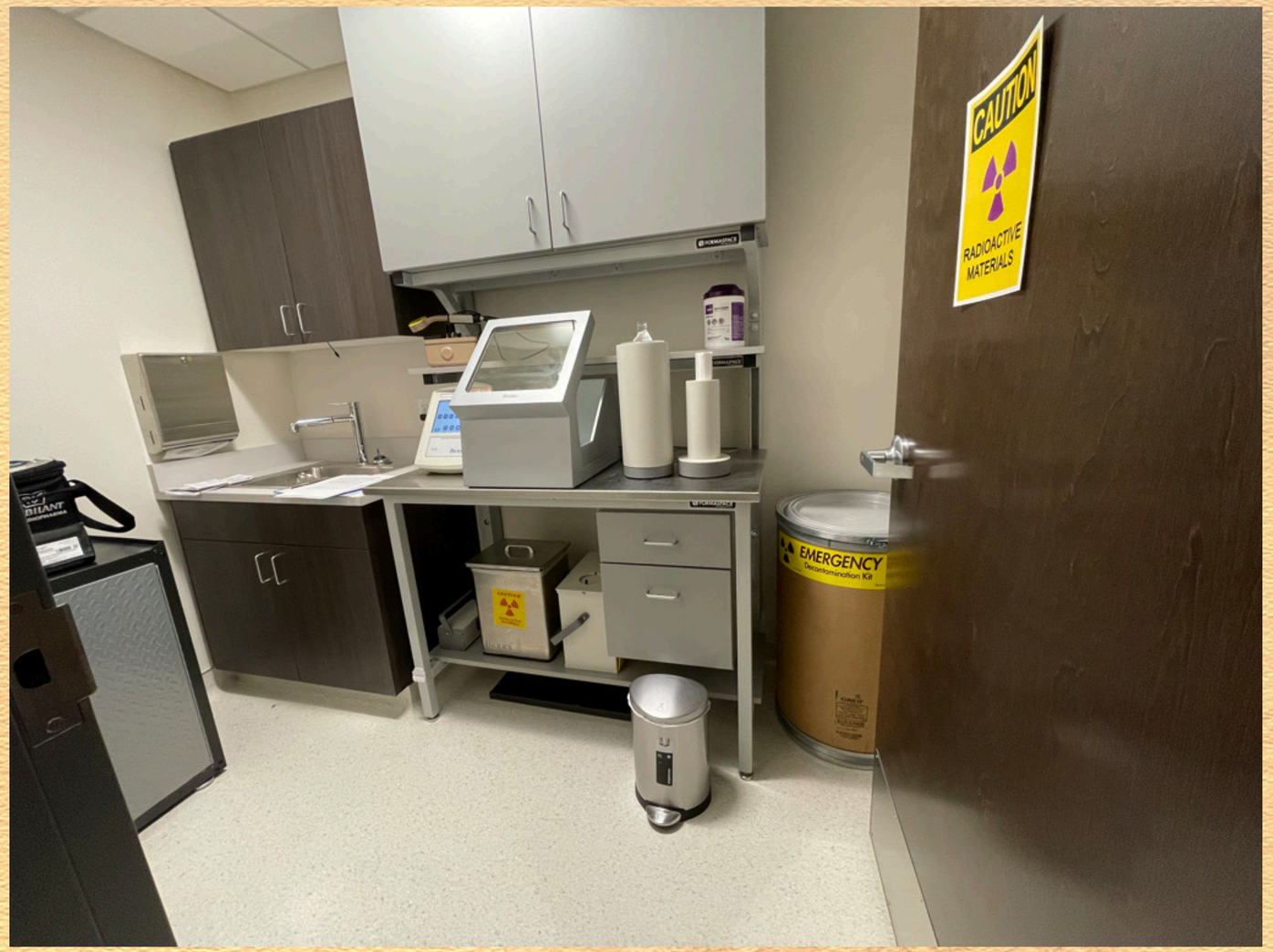
# Tc-99 MAA and $Y^{90}$ Dose Delivery

## 3rd Party Vendor

- Unit Dose delivery
- Limited capital investment
- Limited ongoing maintenance and certification.
- Additional Procedural costs.

## Onsite HotLab

- Capital Investment
- Space
- Certification
- Ongoing Maintenance and Licensing



# HOT LAB REQIREMENTS


**Table 1.** Radiopharmacy Equipment Required for $^{99m}$Tc-MAA Mapping Angiograms and $^{90}$Y Radioembolization Therapies

| Equipment | Purpose |
|---|---|
| Dose calibrator and well counter | Pre-procedure dose assay |
| Co-57 vial source, 10 mCi | Quality control |
| Cs-137 vial source, 250 uCi | Quality control |
| Table-top L-shield | Radiation shielding |
| Extruded lead brick | Radiation shielding |
| Waste container, 0.125-inch lead | Radiation shielding |
| Waste cabinet, 1-inch lead | Radiation shielding |
| Sharps container shield for monoject sharps container, 0.125-inch lead | Radiation shielding |
| Syringe carrier, 0.125-inch lead | Radiation shielding |
| Decontamination kit | Radiation safety |
| Survey meter | Radiation safety |
| Hand/foot monitor detector | Radiation safety |

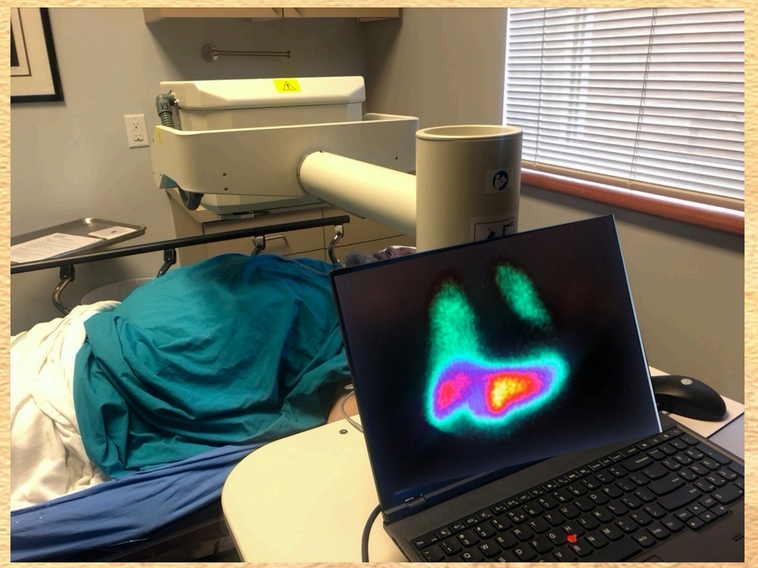
# Onsite Nuclear Imaging?

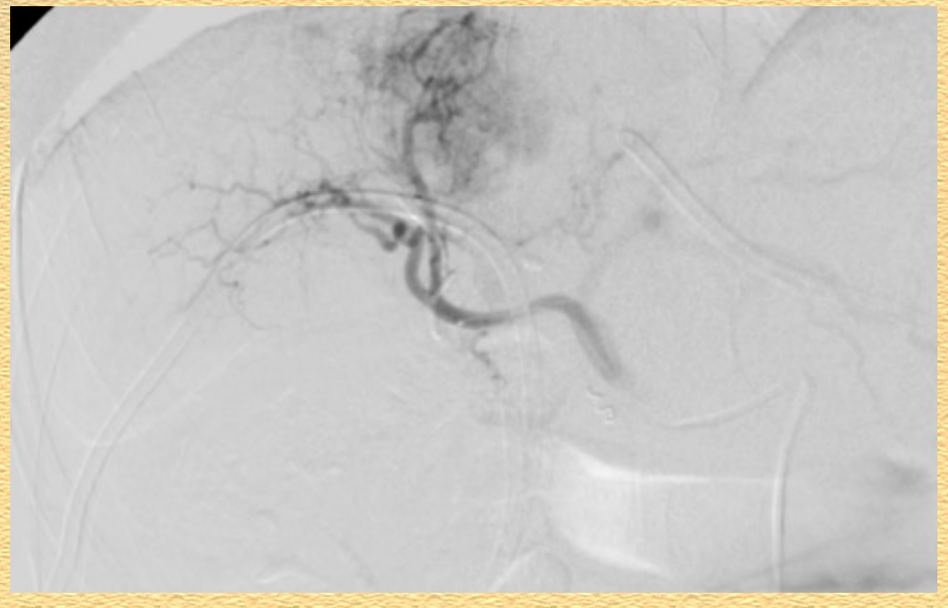
## Facility based

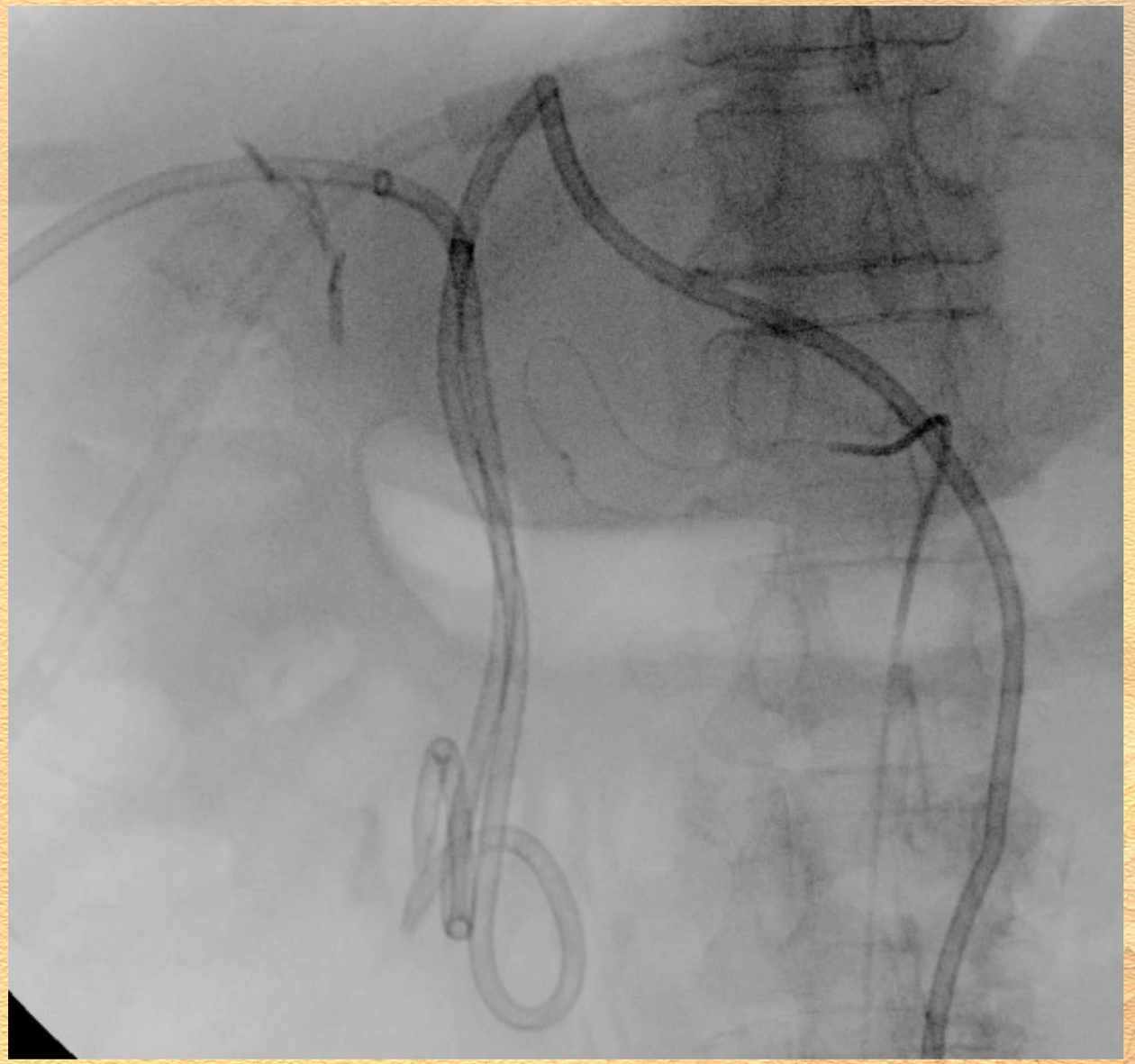
- Capital Investment for Gamma Camera
- Possible Certification Need
- Staffing
- Space Requirements


## Offsite Facility

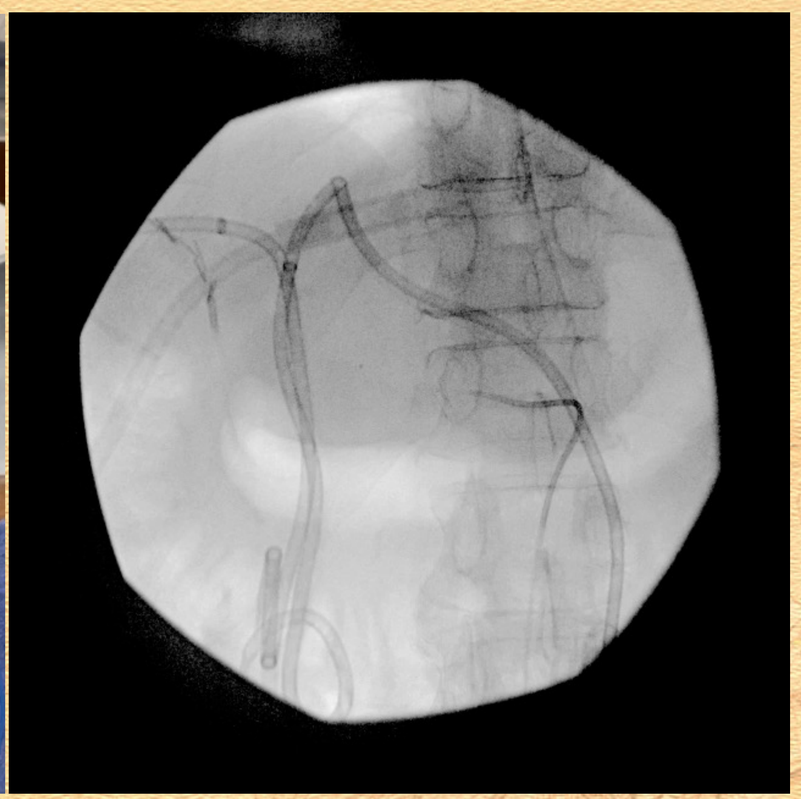
- Proximity to Facility <30min
- Scheduling Flexibility
- Relationship with OP Facility



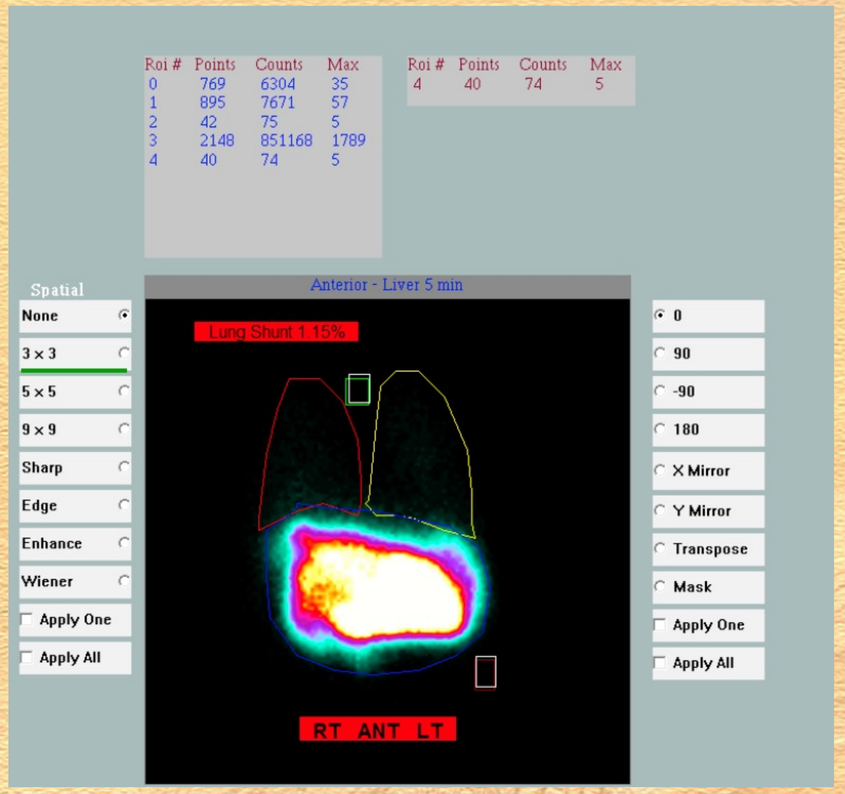




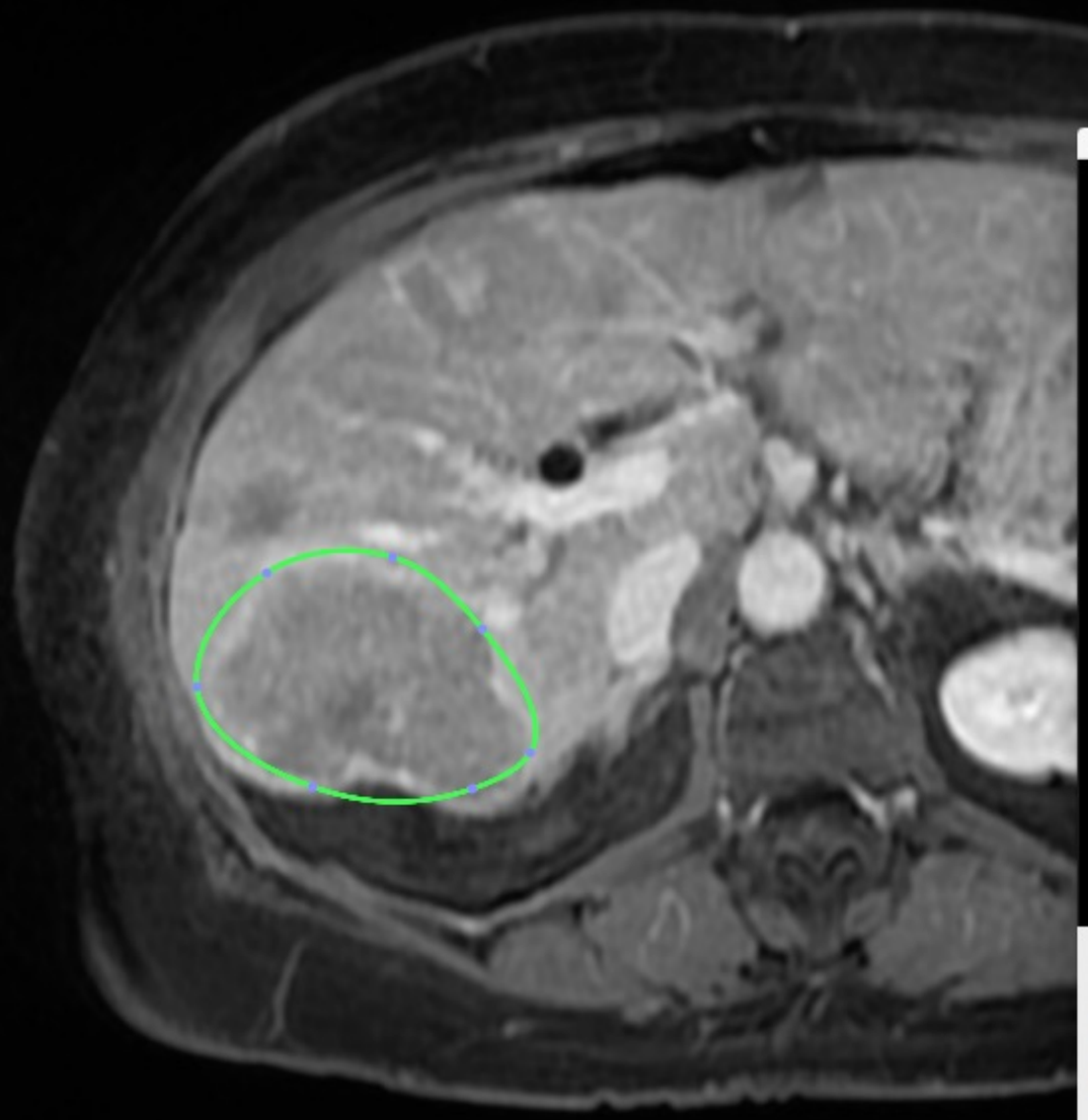
# MAA Infusion

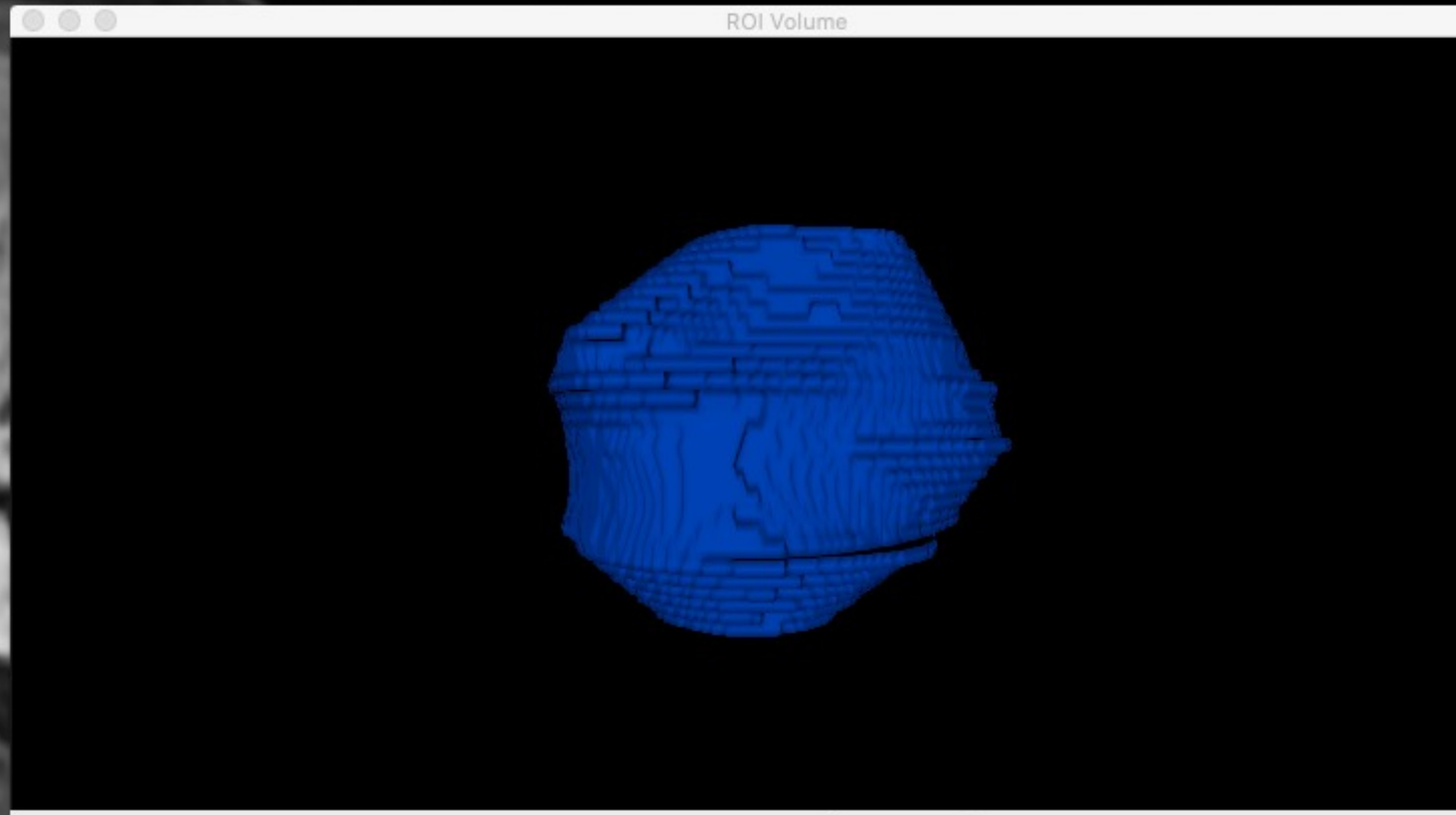



# Portable Gamma Camera

# OSIRIX






**Options:**

- [ ] Show Wireframe
- [x] Color:
- [x] Textured

Opacity:

**Reconstruction Filter:**

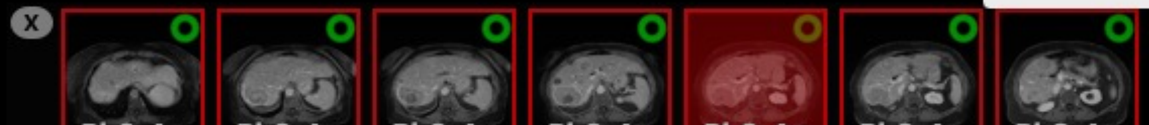
- ( ) Power Crust
- ( ) Delaunay
- (•) Iso Contour

**Statistics:** Histogram

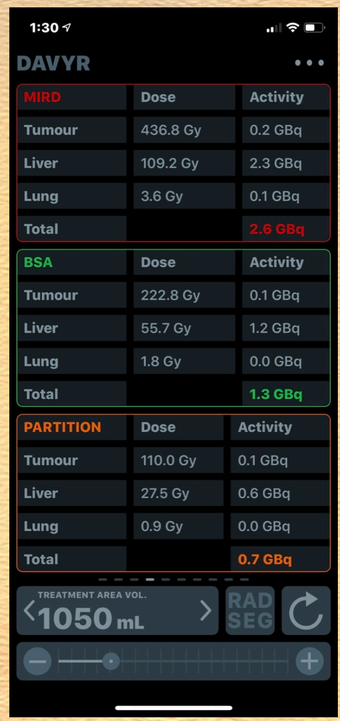
Right lobe tumor
Volume : 186.1610 cm³
Mean: 660.6024 SDev: 113.0790 Total: 82807168.0000
Min: 43.0000 Max: 1205.0000

Series Name: Volume : 186.1610 cm³

Save as DI

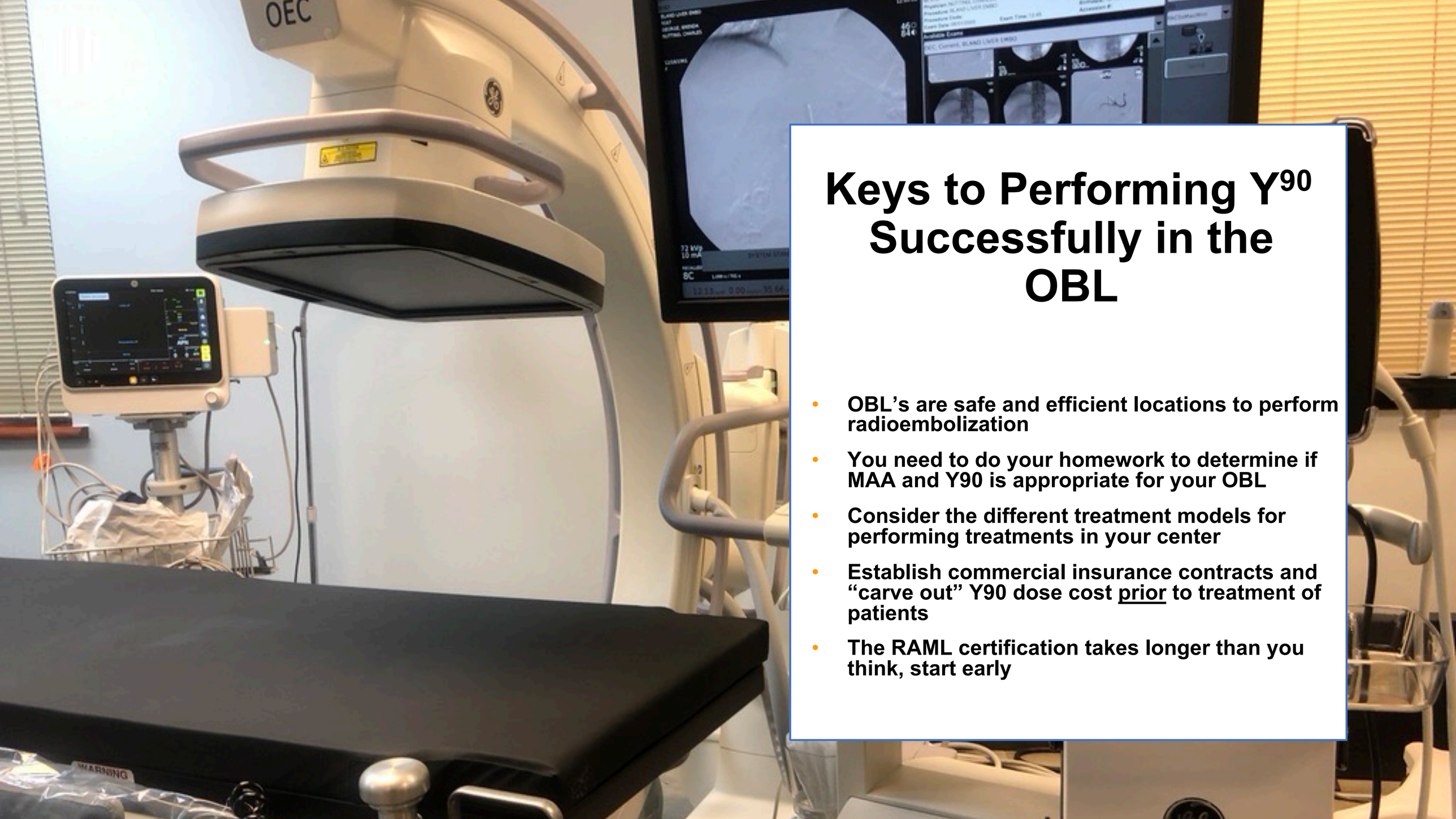







# SMAC, iDOC and DAVYR APP

- July 2020 – July 2021
  - 64 MAA in service site 11
  - 32 Y90’s in service site 11
  - 47 Y90’s in service site 22
- We contracted with commercial insurance and Medicare
- Plan to revisit contracting with additional insurance companies to review potential cost savings




# Keys to Performing $Y^{90}$ Successfully in the OBL

- OBL's are safe and efficient locations to perform radioembolization
- You need to do your homework to determine if MAA and Y90 is appropriate for your OBL
- Consider the different treatment models for performing treatments in your center
- Establish commercial insurance contracts and "carve out" Y90 dose cost prior to treatment of patients
- The RAML certification takes longer than you think, start early