Department of Medical Physics
UNIVERSITY OF WISCONSIN – MADISON
SCHOOL OF MEDICINE AND PUBLIC HEALTH

RED
RADIOLOGICAL ENGINEERING & DESIGN LABORATORY

FDA-Approved (and Upcoming) Dosimetry Software

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AAPM Annual Meeting, San Antonio, TX July 18th, 2019

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Disclosures

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I'm the co-founder and CSO of Voximetry, LCC a Middleton-based nuclear medicine dosimetry company.

Information for this talk based on:

- 75+ customer discovery interviews
- Recent "cold" calls/emails
- Desk research

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Outline

- Background
- Current Dosimetry Workflows
- Customer Needs
- FDA-Cleared Dosimetry Products
- Upcoming Dosimetry Products
- Billing

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Background

When radiopharmaceutical therapy (RPT) fails to produce significant improvement in local control it is primarily due to:

- Tumor selectivity
- Limited radiation tolerance of normal tissues
- Tumor radiosensitivity
- Heterogeneous uptake within the tumor (i.e. heterogeneous dose)

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Background

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Patient-specific dosimetry can improve RPT outcomes

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Background

EU directive 2013/59/EURATOM Article 56 states:

"For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure".

"'radiotherapeutic' means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes"

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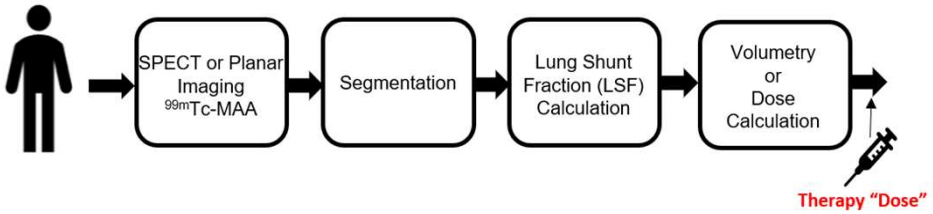
^{90}Y Microsphere Dosimetry Workflows



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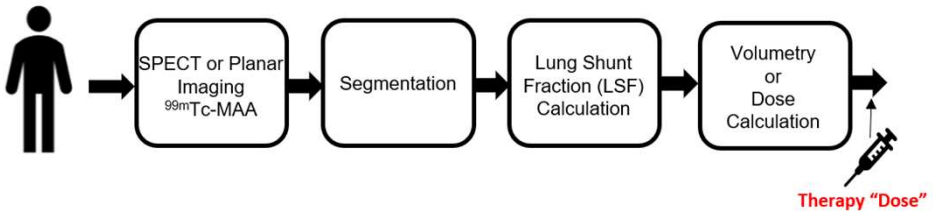
^{90}Y Microsphere Dosimetry Workflows



Constraints

- SIR-Spheres
  - BSA: $A[GBq] = (BSA[m^2] - 0.2) + \frac{V_{tumor}}{V_{liver}}$
  - Partition Model: $A[GBq] = \frac{D_{tissue}[Gy] \times m_{tissue}[kg] \times n}{49.7[Gy-kg/GBq]}$
    - $n = LSF$ for lung
    - $n = (1 - LSF)$ for liver
    - Equilibrium absorbed dose constant
- TheraSphere
  - Partition Model: $A[GBq] = \frac{D_{tissu}\ [Gy] \times m_{tissu}\ [kg] \times LSF}{49.7[Gy-kg/GBq]}$

$D_{liver} = 80\ Gy$

$D_{lung} = 25\ Gy$

$D_{lung} = 30\ Gy$

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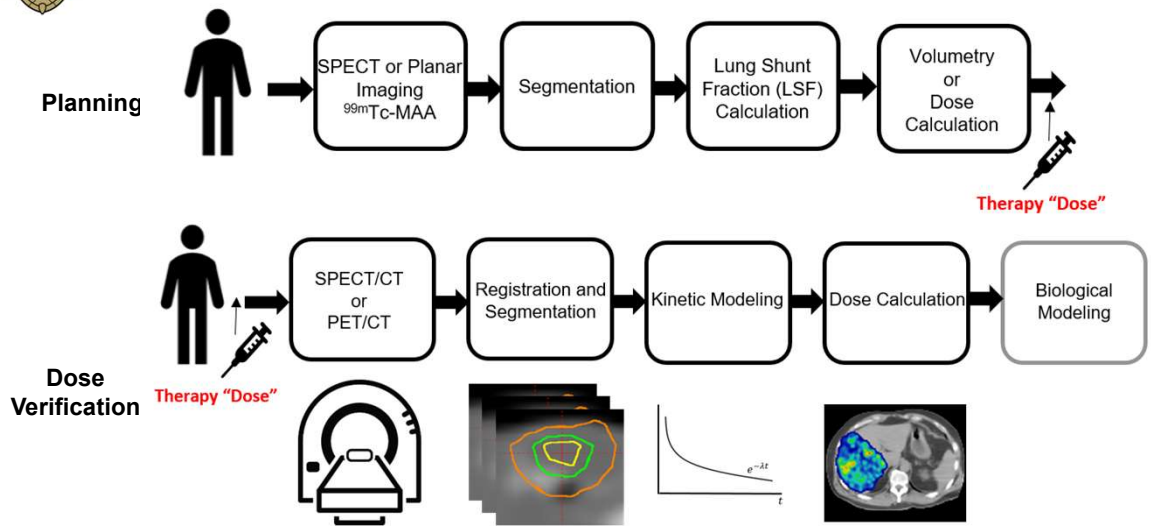
^{90}Y Microsphere Dosimetry Workflows



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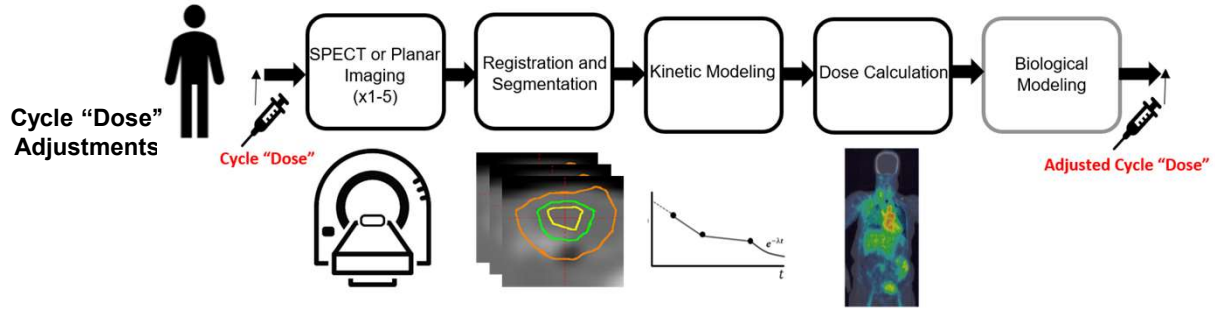
Systemic RPT Dosimetry Workflow



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Customer Needs

- **Image Reconstruction**
  - Attenuation Correction
  - Scatter Correction
  - Resolution Recovery
- **Registration**
  - Rigid
  - Affine
  - Deformable
- **Segmentation**
  - Manual
  - Semi-automated
  - Automated
- **Kinetic Modeling**
  - Trapazoidal Integration
  - Curve Fitting
  - PK Modeling
- **Dose Calculation**
  - Phantom-based
  - Voxel-based
    - Local Energy Deposition
    - Dose Kernel or Voxel S-Value
    - Direct Monte Carlo
- **Biological Modeling**
  - BED
  - EUD

FDA-Cleared Dosimetry Software

Company	Product(s)	Image Reconstruction	Registration	Segmentation	Kinetic Modeling	Dose Calculation	Clearance
Hermes Medical Solutions	Hybrid3D™ SIRT	Vendor Neutral Attenuation Correction Scatter Correction Resolution Recovery	Multi-modality rigid and "focused" based	Semi-automated	Physical Decay	Local Energy Deposition – ^{90}Y	510(k) Clearance (July 2017)
	Hybrid Dosimetry™ OLINDA/EXM 2.0®				Exponential Bi-Exponential Trapezoidal	OLINDA 2.0 'Semi' Monte Carlo under FDA review	
MIMs	SurePlan™ LiverY90	Vendor Neutral Attenuation Correction Scatter Correction Resolution Recovery	Multi-modality rigid and deformable	Manual Semi-automated Automated	Physical Decay	Local Energy Deposition – ^{90}Y	510(k) Clearance (Nov. 2017) 510(k) Clearance (Dec. 2018)
	SurePlan™ MRT				Exponential Bi-Exponential Trapezoidal	Voxel S-Value – ^{177}Lu and ^{131}I	
Varian	Velocity™ RapidSphere	NA	Multi-modality rigid and deformable	Manual Semi-automated Automated	Physical Decay	Local Energy Deposition – ^{90}Y	510(k) Clearance (Feb. 2018)

NA = Not Available

FDA-Cleared Dosimetry Software

Company	Product(s)	Image Reconstruction	Registration	Segmentation	Kinetic Modeling	Dose Calculation	Clearance
Mirada	Simplicit90Y™ XD Nucl Med	NA	Multi-modality rigid and deformable	Manual Semi-automated Automated	Physical Decay	Local Energy Deposition – ^{90}Y	510(k) Clearance (Dec. 2018)
Dosisoft	PLANET® Dose	NA	Multi-modality rigid and deformable	Manual Semi-automated Automated	Physical Decay	Local Energy Deposition and Voxel S-Values – ^{90}Y	510(k) Clearance (Mar. 2019)

NA = Not Available

Emerging Products

- Philips Healthcare Stratos (Part of Imalytics Research Workstation)
- Siemens Healthineers' Dosimetry Research Tool*
- SurgicEye DosePlan
- Rapid, LLC
- Voximetry, Inc.

*Investigational device not commercially available

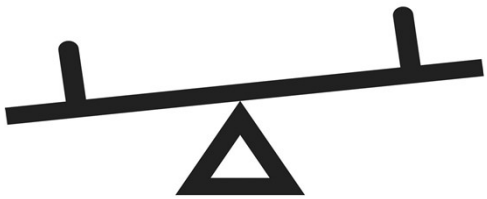
Reimbursement

EBRT CPT® Planning Codes

77261, 77263, 77280,
77290, 77293, 77295,
77300, 77331, 77301,
77338, 77306, 77307,
77321, 77332, 77334,
77336, 77370*

Nuclear Medicine CPT® Planning Codes

77370*
77300
77295



*Special medical radiation physics consultation ($125.35)

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SAM Question # 1

1) The OLINDA/EXM software is now distributed by:

   a. Varian Medical Systems
   b. Hermes Medical Solutions
   c. Dosisoft
   d. MIM Software Inc.

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SAM Question # 1

1) The OLINDA/EXM software is now distributed by:

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b. Hermes Medical Solutions
c. Dosisoft
d. MIM Software Inc.

Answer: **(b)**

Reference: Huizing et al. “Dosimetry methods and clinical applications in peptide receptor radionuclide therapy for neuroendocrine tumours: a literature review” EJNMMI Research (2018) 8:89

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SAM Question # 2

1) Commercial voxel-level dosimetry software is primarily being used to:

a. Verify dose distributions from selective internal radiation therapy
b. Perform treatment planning calculations for selective internal radiation therapy
c. Verify dose distributions from systemically delivered RPT agents (e.g. Lutathera®)
d. Perform treatment planning calculations for systemically delivered RPT agents (e.g. Lutathera®)

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SAM Question # 2

1) Commercial voxel-level dosimetry software is primarily being used to:

a. Verify dose distributions from selective internal radiation therapy
b. Perform treatment planning calculations for selective internal radiation therapy
c. Verify dose distributions from systemically delivered RPT agents (e.g. Lutathera®)
d. Perform treatment planning calculations for systemically delivered RPT agents (e.g. Lutathera®)

Answer: **(a)**

Reference: Kafrouni et al. "Retrospective voxel-based dosimetry for assessing the body surface area model ability to predict delivered dose and radioembolization outcome" J Nucl Med. (2018) 59(8):1289-1295

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References

FDA Clearance notification letters for DOSIsoft, Mirada Medical Ltd., Varian Medical Systems, Inc, Hermes Medical Solutions AB, MIM Software Inc.

Kappadatch SC, "Yytrium-90 microsphere therapy planning and dose calculations", AAPM Annual Meetin 2011

McMeekin H. "Calculation methods in Hermes Medical Solution's dosimetry software", MRTDosimetry Workshop 2018

Jenkins L. "HERMES Dosimetry Software" 3rd MRTDosimetry Workshop 2015

Bose S. "Velocity™ 4.0", AAMD Spring Regional Meeting 2018

Velocity Feature Sheet
https://www.varian.com/sites/default/files/resource_attachments/VelocityFeatureSheet_RAD_10569_June2018_Secured.pdf

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Acknowledgements

Acknowledgements

RED Lab Team
Joseph Grudzinski
Ian Marsh
Andrew Shepard
Charlie Matrosic
David Adam
Sydney Jupitz
Sabrina Hoffman
Abby Besemer
Jamey Weichert
Renier Hernandez
Zach Morris
Peter Carlson
Paul Sondel
Mario Otto
Dana Baiu
Lance Hall
Paul Harari
Paul Wickre

Thank You!

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Background

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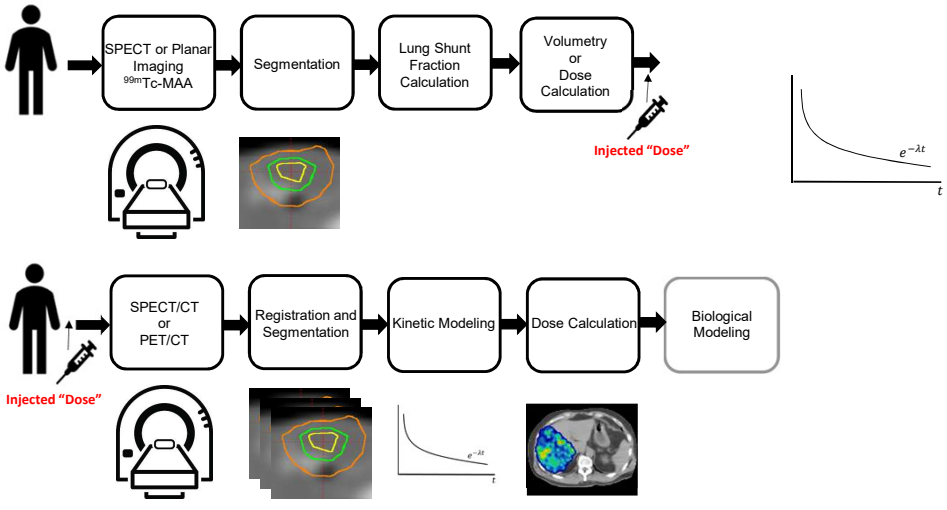

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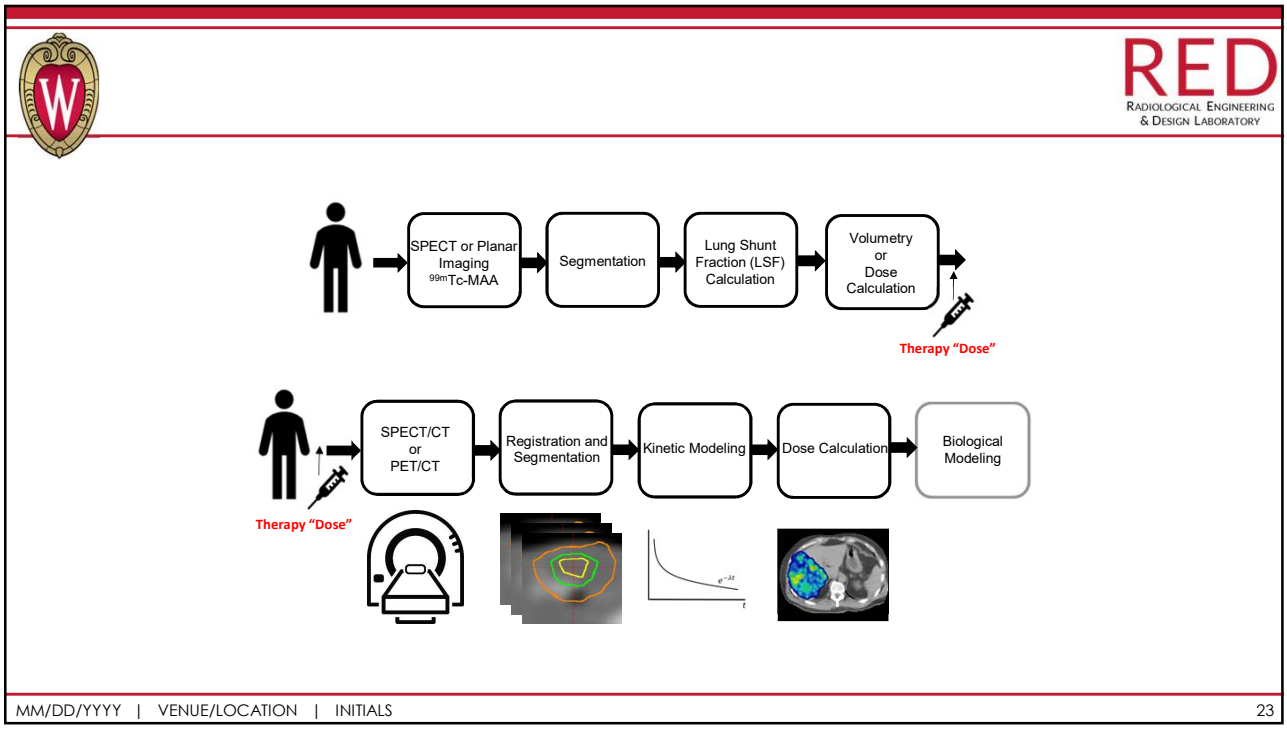
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Radiological Engineering & Design Laboratory
SPECT or Planar Imaging 99mTc-MAA
Segmentation
Lung Shunt Fraction (LSF) Calculation
Volumetry or Dose Calculation
Therapy "Dose"
SPECT/CT or PET/CT
Registration and Segmentation
Kinetic Modeling
Dose Calculation
Biological Modeling
Therapy "Dose"
MM/DD/YYYY | VENUE/LOCATION | INITIALS
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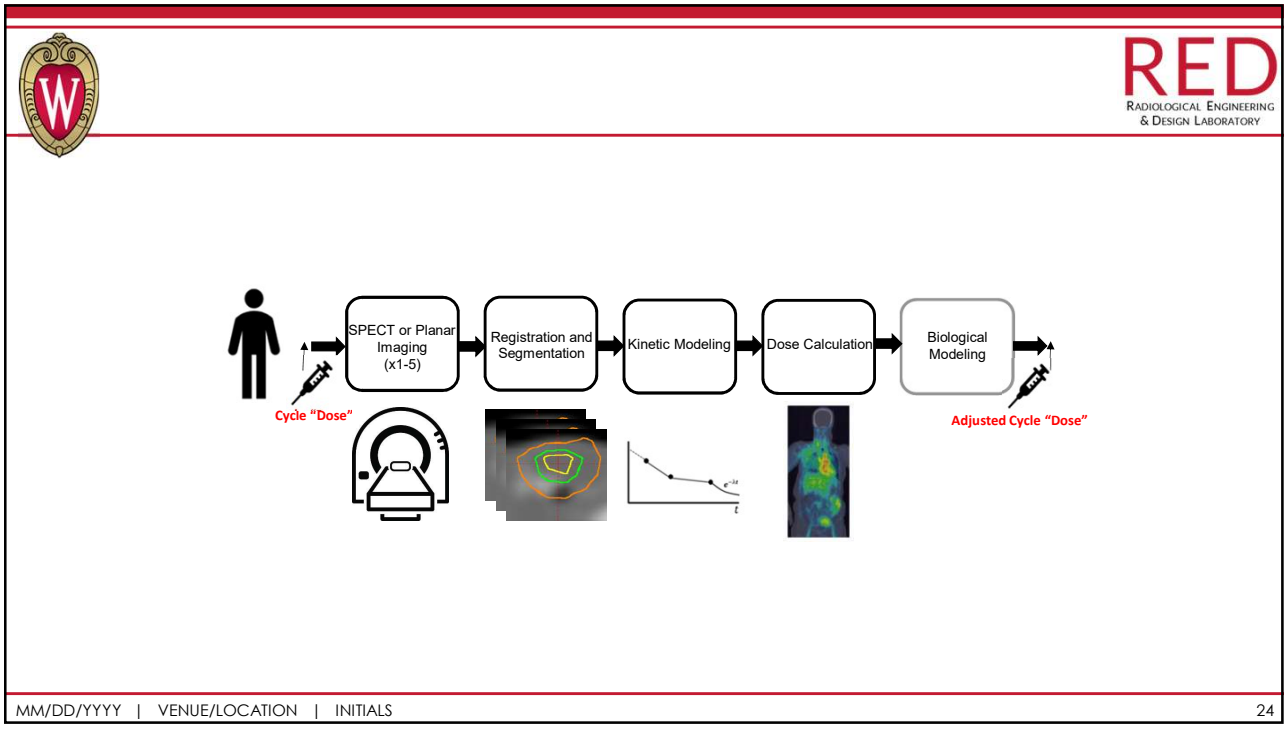
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Radiological Engineering & Design Laboratory
SPECT or Planar Imaging (x1-5)
Registration and Segmentation
Kinetic Modeling
Dose Calculation
Biological Modeling
Cycle "Dose"
Adjusted Cycle "Dose"
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