Intravascular Brachytherapy (IVBT) 101: Commissioning and QA

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Disclosure

- None

Outline

- Discuss key steps to initiate an IVBT program
  - Licensing
  - Commissioning
- Discuss quality assurance checks

Licensing requirements

- License application/amendment for medical use of byproduct material under 10 CFR 35.1000 (“Other medical uses”) should be submitted

https://www.nrc.gov/materials/miau/med-use-toolkit/intravascular.html

Licensing requirements

- License application/amendment for medical use of byproduct material under 10 CFR 35.1000 (“Other medical uses”) should be submitted
- Authorized User (AU) physician should meet training and experience under 10 CFR 35.690 (remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units)

https://www.nrc.gov/materials/miau/med-use-toolkit/intravascular.html

Licensing requirements

- AU, interventional cardiologist, and Authorized Medical Physicist (AMP) should complete vendor training
  - Device operation
  - Safety procedures
  - Clinical use
  - Treatment planning

https://www.nrc.gov/materials/miau/med-use-toolkit/intravascular.html

Licensing requirements

- AU, interventional cardiologist, and Authorized Medical Physicist (AMP) should complete vendor training
  - Device operation
  - Safety procedures
  - Clinical use
  - Treatment planning
- Develop written procedures, should include:
  - Emergency procedures for stuck and detached sources
  - Procedures for “source stepping,” if used

https://www.nrc.gov/materials/miau/med-use-toolkit/intravascular.html

Licensing requirements

- Secure, locked storage location should be identified and used for the transfer devices when not in use
- AMP should assay source and verify its output before first patient treatment
- Surveys should be conducted of patient and delivery catheter
- Note: Shielding calculation not necessary since Sr-90 is a pure beta emitter

https://www.nrc.gov/materials/miau/med-use-toolkit/intravascular.html

Commissioning

- Dose calculations
- Source assay
- Source uniformity
- Documentation
  - Policies and procedures
  - Written directive
  - Survey form
  - Checklists

Nath *et al.*, Med Phys, 26(2); 1999: 119 – 152
Chakri & Thomadsen, Med Phys, 29(12); 2002: 2850 – 2860
Chiu-Tsao *et al.*, Med Phys, 34(11); 2007: 4126 - 4157

Dose Calculation - Simple

- Based on absorbed dose rate in water per unit activity at a depth of 2mm
  - 30 mm: 0.154 Gy min^{-1} mCi^{-1}
  - 40 mm: 0.113 Gy min^{-1} mCi^{-1}
  - 60 mm: 0.0746 Gy min^{-1} mCi^{-1}

Chiu-Tsao *et al.*, Med Phys, 34(11); 2007: 4126 - 4157

ORDER # (REF):TDA-2040

Jacketed Radiation Source Train (JRST)
Description: SICW.2.H 40 : series of 16 Model SICW.2 sealed sources jacketed in a stainless steel coil (0.47 mm OD) with non-radioactive radiopaque marker welded to each end.
Radionuclide: Sr-90

Active Length: 40mm

Total Activity: 2.11 GBq **Assay Date: 20May02**

Recommended Radiation Treatment

Transfer Device Serial #: 91456 **Radiation Source Train Serial #: ZA673**

Effective Date From: 31Aug21 To: 03Mar22

	Maximum Balloon Diameter (mm)	Reference Vessel Diameter (mm)	Dose @ 2mm (Gray)	Dwell Time (Secs) or (Mins, Secs)	
With Existing Stent	≥ 2.5 to < 3.5	≥ 2.7 to ≤ 3.35	18.4	283	4, 43
	≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	353	5, 53

Use the following treatment chart ONLY after the required six month Leak Test is completed.

Effective Date From: 04Mar22 To: 31Aug22

	Maximum Balloon Diameter (mm)	Reference Vessel Diameter (mm)	Dose @ 2mm (Gray)	Dwell Time (Secs) or (Mins, Secs)	
With Existing Stent	≥ 2.5 to < 3.5	≥ 2.7 to ≤ 3.35	18.4	286	4, 46
	≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	358	5, 58

NOTE: If the ratio of the maximum balloon diameter to reference vessel diameter is between 1/1 and 1/1.2, dose can be prescribed according to balloon diameter. Dose can also be administered by visual assessment of reference vessel diameter.

Radiation Output: 0.1041 Gy-s^{-1} ± 20% in H_2O at 2 mm from the center line of the Radiation Source Train. Date: 20May02

Example

Calculate the time to deliver 18.4 Gy at depth of 2 mm (40 mm source train):

- Ao = 2.11 GBq = 57 mCi (May 20, 2002)
- A = 35.6 mCi (Sept 9, 2021, date of assay)

- 0.113 Gy min^{-1} mCi^{-1} = 1.88e-3 Gy s^{-1} mCi^{-1}

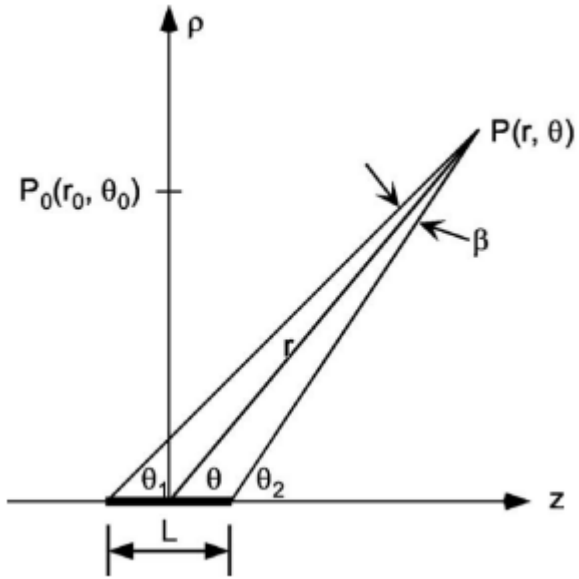
$$t(s) = \frac{s\ mCi}{1.88 \times 10^{-3}\ Gy} \times \frac{1}{35.6\ mCi} \times 18.4\ Gy = 275\ s$$

Dose Calculation - Complex

To calculate dose around the source, utilize the TG-60 formalism:

$$D(r,\theta) = D(r_o,\theta_o) \times \frac{G(r,\theta)}{G(r_o,\theta_o)} \times g(r) \times F(r,\theta)$$

- r_o = 2mm and $\theta_o = \pi/2$
- g(r) – TG 149 (Table II or III)
- F(r, θ) – TG 149 (Table V)



2.5 mm

Nath *et al.*, Med Phys, 26(2); 1999: 119 – 152
Chiu-Tsao *et al.*, Med Phys, 34(11); 2007: 4126 – 4157
Thomadsen, "Quality Management for Intravascular Brachytherapy," 2001 Annual AAPM Meeting

Novoste™ **Active Transfer Device** within White Lead-Lined Storage Container BETA-CATH SYSTEM

ORDER # (REF):TDA-2040

Jacketed Radiation Source Train (JRST) Active Length: 40mm
Description: SICW.2.H 40 : series of 16 radiopaque marker welded to each end. Model SICW.2 sealed sources jacketed in a stainless steel coil (0.47 mm OD) with non-radioactive
Radionuclide: Sr-90 **Total Activity: 2.11 GBq** **Assay Date: 20May02**

Recommended Radiation Treatment

Transfer Device Serial #: 91456 **Radiation Source Train Serial #: ZA673**

Effective Date From: 31Aug21 **To: 03Mar22**

	Maximum Balloon Diameter (mm)	Reference Vessel Diameter (mm)	Dose @ 2mm (Gray)	Dwell Time (Secs) or (Mins, Secs)	
With Existing Stent	≥ 2.5 to < 3.5	≥ 2.7 to ≤ 3.35	18.4	283	4, 43
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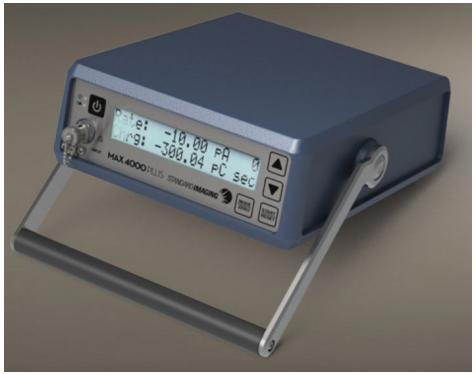
Source Assay

- Assay should be performed with a well chamber and electrometer that is calibrated for a Beta-Cath source train

IVBT Source Holder



Well Chamber Calibration Coefficient (ADCL)

Standard Imaging
Model: IVB1000
S/N: H171531

Standard Imaging, Inc.
Model: SUPERMAX
S/N: P111024

Type	:	Well-type
Atmospheric Communication	:	Open
Calibration Source	:	Beta-Cath 3.5 French 30mm Source Train
Source Dose Rate	:	69.0 mGy/s
Source Holder Used	:	Novoste holder, 042727
Source Reference Point	:	Position 30
Collecting Electrode Bias	:	+300 V
Charge Collected	:	Negative
Pre-Irradiation Leakage	:	-1.0×10^{-15} A
Calibration Uncertainty	:	15.3 %

Calibration Coefficient (at 22 °C and 101.325 kPa)

Absorbed Dose to Water @ 2 mm Calibration Coeff.: **3.195×10^{10}** mGy/s/A

40mm Absorbed Dose to Water Calibration Coefficient = 0.75 x 30mm Calibration Coefficient
60mm Absorbed Dose to Water Calibration Coefficient = 0.50 x 30mm Calibration Coefficient

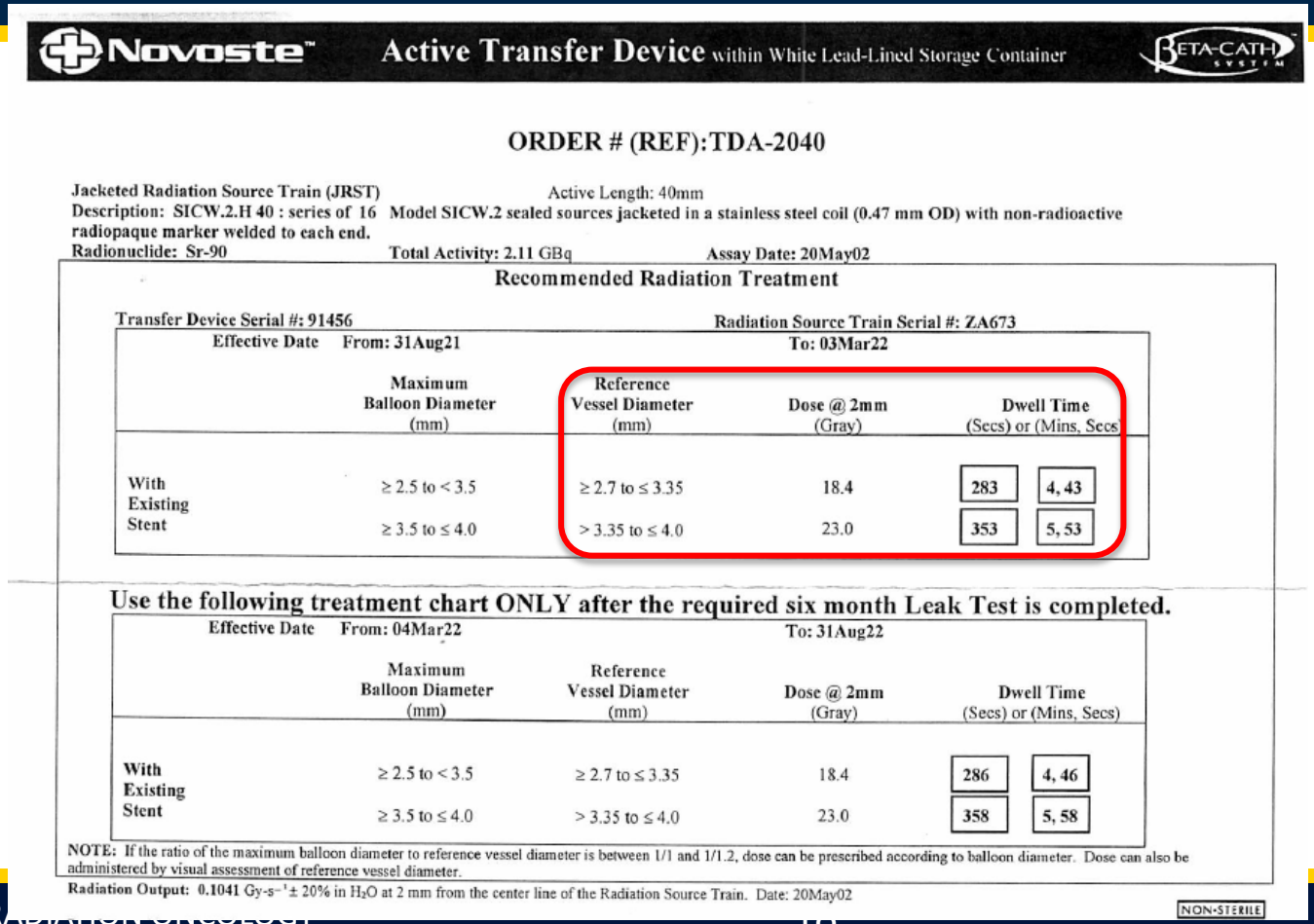
Source Assay

1. Acquire rate measurements of extended source
2. Calculate dose rate

$$Dose\ Rate = Rdg \times N_{Dw,2mm}\left(\frac{mGy}{s\ A}\right) \times ECF\left(\frac{A}{Rdg}\right) \times C_{T,P} \times Geom\ Factor \times Decay\ Factor$$

3. Calculate dwell times and compare dwell times with values specified on calibration certificate

Source Assay



Novoste™ Active Transfer Device within White Lead-Lined Storage Container BETA-CATH SYSTEM

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Radionuclide: Sr-90 Total Activity: 2.11 GBq Assay Date: 20May02

Recommended Radiation Treatment

Transfer Device Serial #: 91456 Radiation Source Train Serial #: ZA673

Effective Date From: 31Aug21 To: 03Mar22

	Maximum Balloon Diameter (mm)	Reference Vessel Diameter (mm)	Dose @ 2mm (Gray)	Dwell Time (Secs)	Dwell Time (Mins, Secs)
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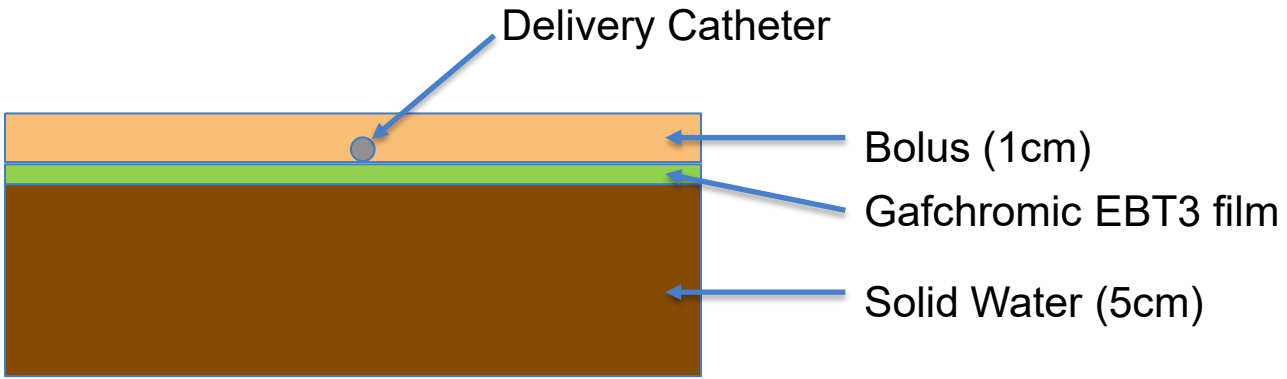
Radiation Output: 0.1041 Gy-s^{-1} ± 20% in H_2O at 2 mm from the center line of the Radiation Source Train. Date: 20May02

NON-STERILE

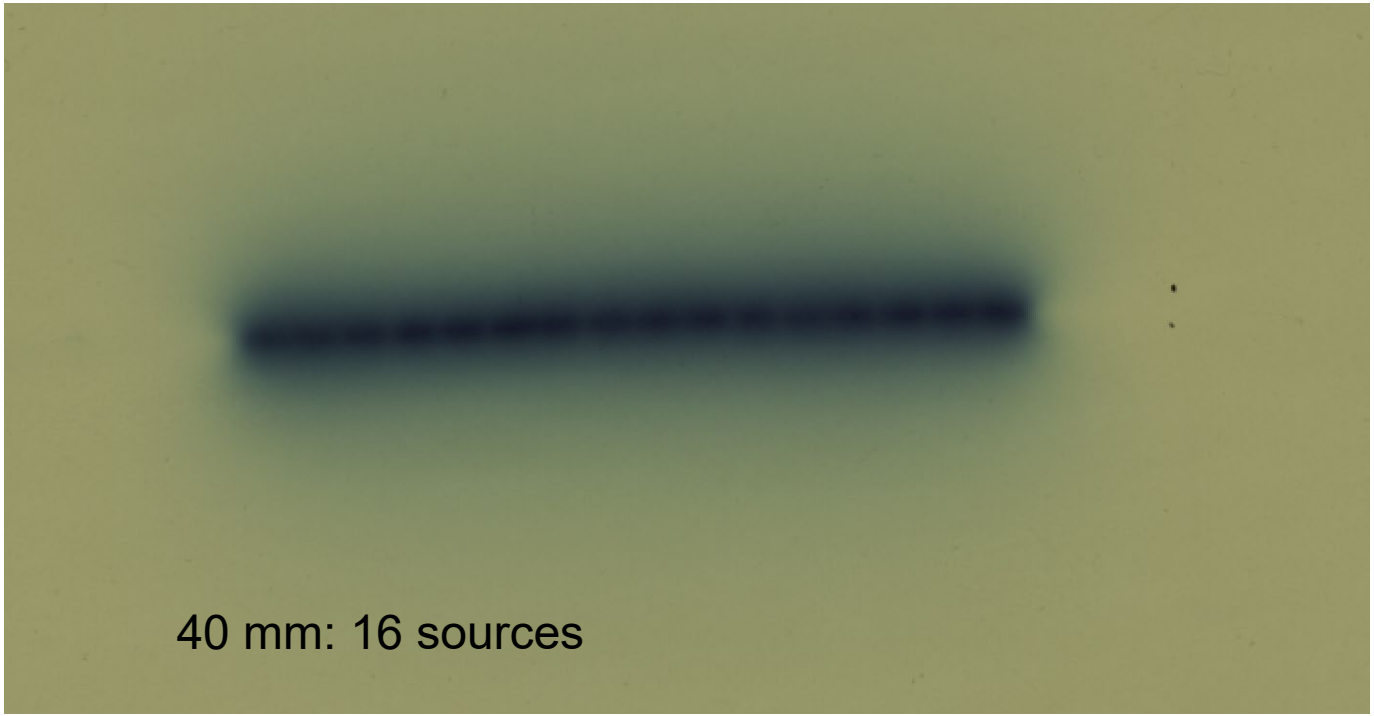
Calc'ed Dwell Times (s)	% Diff
285.3	-0.8
356.7	-1.0

Source Uniformity Setup

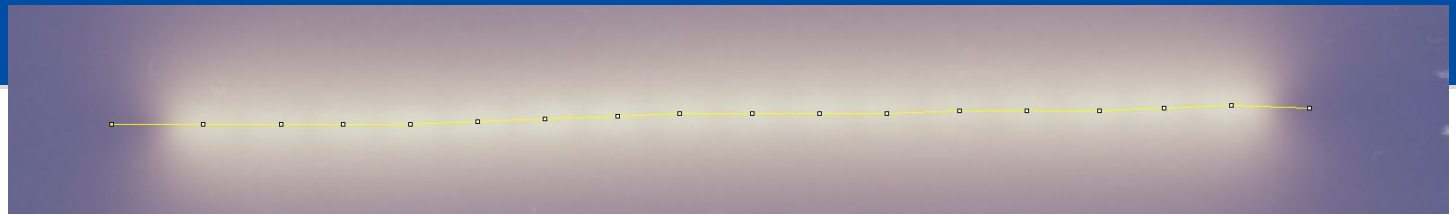


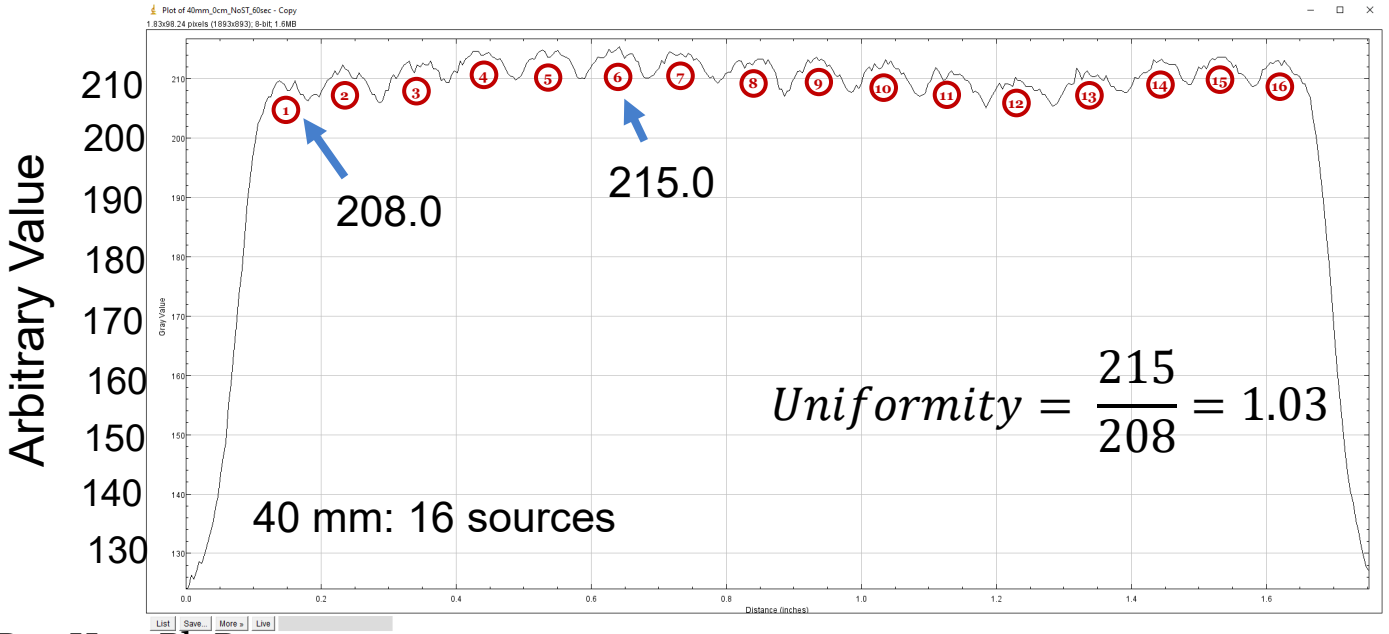
Courtesy of Dae Han, Ph.D.

40 mm source train (16 sources)



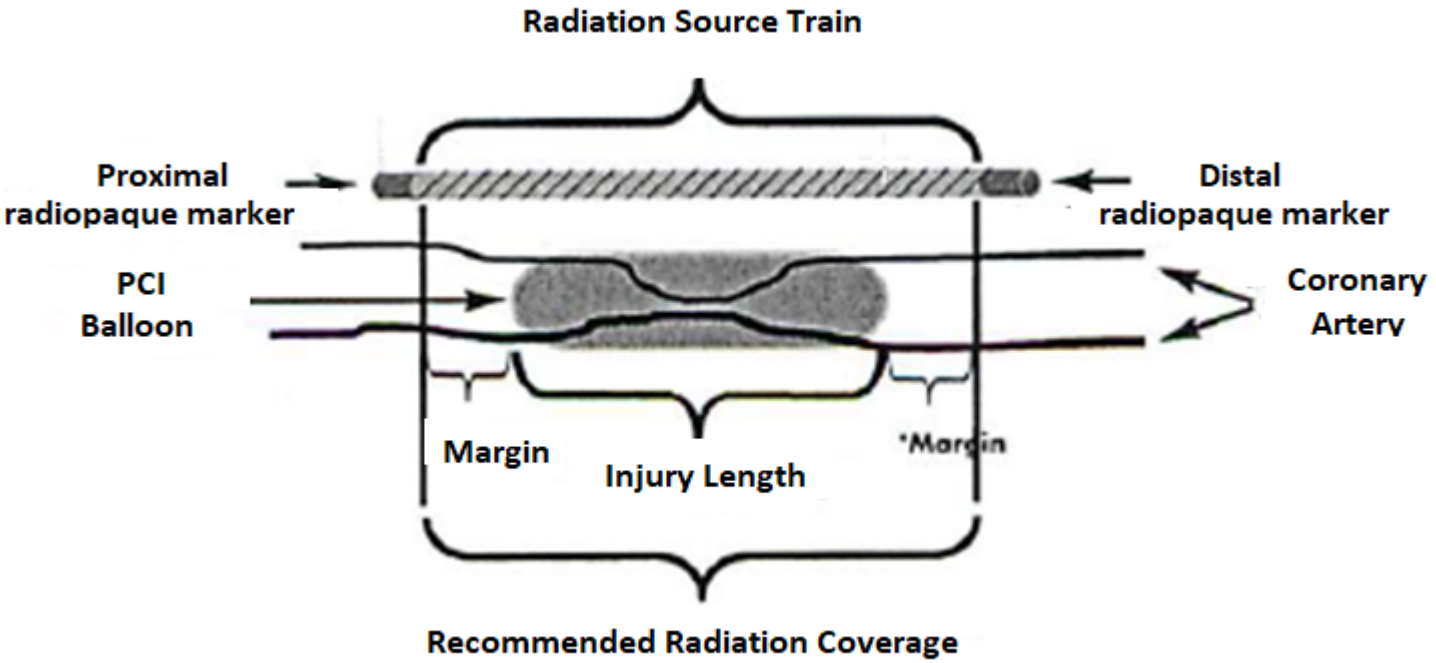
Courtesy of Dae Han, Ph.D.





Courtesy of Dae Han, Ph.D.

Selection of Source Train Length



Best Vascular, Inc.

Selection of Source Train Length

a) 5 mm margin:

Source Train	Injured Length
30 mm	0 to 20 mm
40 mm	0 to 30 mm
60 mm	0 to 50 mm

b) 10 mm margin:

Source Train	Injured Length
30 mm	0 to 10 mm
40 mm	0 to 20 mm
60 mm	0 to 40 mm

Best Vascular, Inc.

Selection of Source Train Length

a) 5 mm margin:

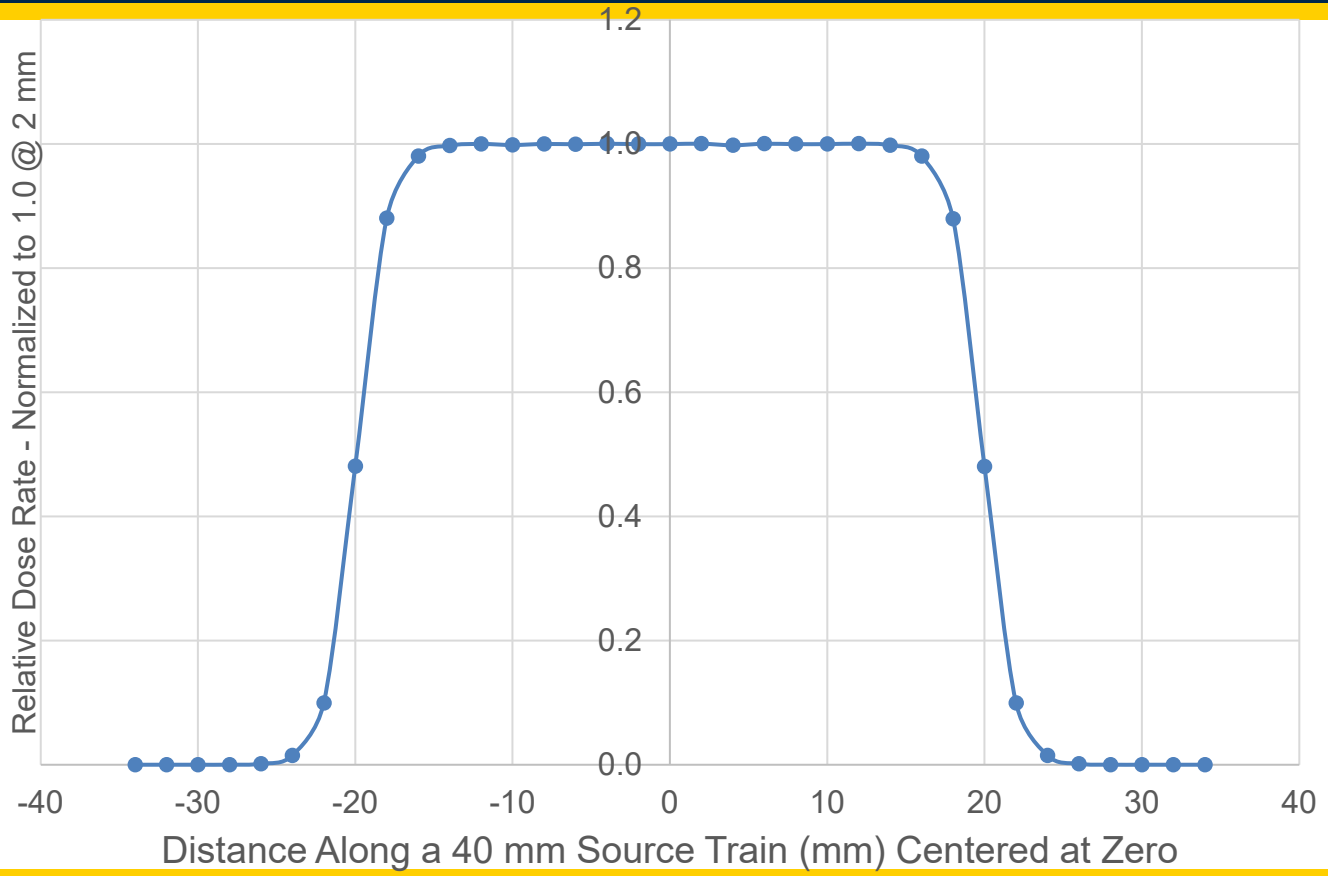
Source Train	Injured Length
30 mm	0 to 20 mm
40 mm	0 to 30 mm
60 mm	0 to 50 mm

b) 10 mm margin:

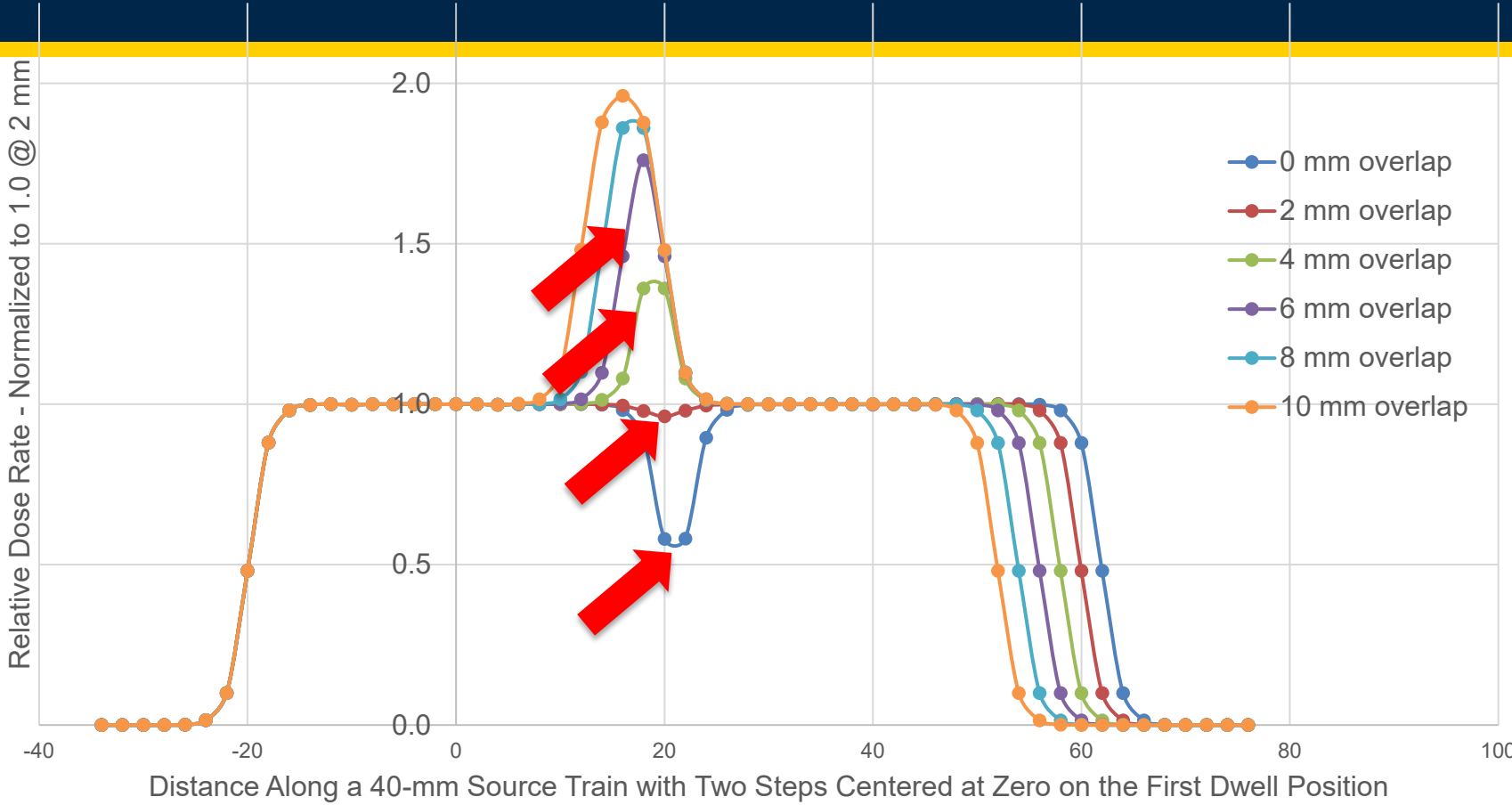
Source Train	Injured Length
30 mm	0 to 10 mm
40 mm	0 to 20 mm
60 mm	0 to 40 mm

Best Vascular, Inc.

Dose Profile – 40 mm Source Train



Dose Profile – 2 Dwell Positions of a 40 mm Source Train



Selection of Source Train Length and # of Dwell Positions

Maximum Injury Length that can be treated with a given source train:

$$n \times TL(mm) - DM(mm) - PM(mm) - (n - 1) \times OL(mm)$$

n = # of dwell positions
TL = source train length
DM = distal margin
PM = proximal margin
OL = length of overlap between dwell positions

Selection of Source Train Length and # of Dwell Positions

b) 10 mm margin± and 5 mm overlap (default):

Source Train	Injured Length	Pull Back
40 mm	**0 to 20 mm**	**N/A**
60 mm	**20.1 to 40 mm**	**N/A**
2 x 40 mm	**40.1 to 55 mm**	**35 mm**
3 x 40 mm	55.1 to 90 mm	35 mm each
2 x 60 mm	**55.1 to 95 mm**	**55 mm**
3 x 60 mm	95.1 to 150 mm	55 mm each

a) 5 mm margin± and 5 mm overlap:

Source Train	Injured Length	Pull Back
40 mm	**0 to 30 mm**	**N/A**
60 mm	**30.1 to 50 mm**	**N/A**
2 x 40 mm	**50.1 to 65 mm**	**35 mm**
3 x 40 mm	65.1 to 100 mm	35 mm each
2 x 60 mm	**65.1 to 105 mm**	**55 mm**
3 x 60 mm	105.1 to 160 mm	55 mm each

Documentation

- Prior to clinical use, policies and procedures should be developed
  - Policy
    - Patient population and eligibility criteria
    - Training requirements – device and radiation safety
    - Source assay requirements – frequency, and by whom
    - Treatment supervision
    - Survey requirements
    - Role of each team member
  - Procedures
    - General workflow
    - Emergency procedures

Documentation

- Written directive
  - Patient name
  - Treatment site
  - Radionuclide
  - Dose, or source strength and exposure time
  - Date
  - Specifics for IVBT
    - Reference vessel diameter
    - Injury length
    - Number of dwell positions

https://www.nrc.gov/materials/miau/med-use-toolkit/intravascular.html
https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0040.html

PATIENT INFORMATION:

Patient Name: _____ Reg. #: _____

Patient's DOB: _____ Physicians' Name(s): _____

SOURCE INFORMATION:

Source: Sr-90/Y-90 (AEAT Model SICW.2) Half-life: 28.8 y

TREATMENT INFORMATION:

Patient Identity Confirmation (at least two required)
[ ] Name [ ] Birth date [ ] Wrist Band Initials: _____

Treatment Site: _____ (see NDCR Segment Diagram)

Reference Vessel Diameter (mm): _____ Injury Length (mm): _____

SINGLE DWELL POSITION (choose one) *

Select	Vessel Diameter (mm)	Dose (Gy) to 2mm radial distance	Source Train Length (mm)	Source SN / RT #	Treatment Time (Effective dates: (04Mar22 to 31Aug22)
☐	2.7 to 3.35	18.4	40	ZA673 / 2021-106	4 min 46 sec
☐	2.7 to 3.35	18.4	60	ZB301 / 2021-107	4 min 43 sec
☐	3.35 to 4.0	23	40	ZA673 / 2021-106	5 min 58 sec
☐	3.35 to 4.0	23	60	ZB301 / 2021-107	5 min 53 sec
☐	4.0 to 5.0	34.2	40	ZA673 / 2021-106	8 min 52 sec
☐	4.0 to 5.0	34.2	60	ZB301 / 2021-107	8 min 46 sec

* A minimum 5 mm distal and proximal margin is recommended.

IF MULTIPLE STEPS (IF TREATMENT LENGTH > SOURCE TRAIN) **

Number of Steps: ____ 2 _____ 3 (Please check appropriate option, if necessary)

** In the overlap region, the dose may be as high as 200% of the prescription dose.

Step 1: Actual Tx time (stopwatch) _____

Step 2: Actual Tx time (stopwatch) _____

Step 3: Actual Tx time (stopwatch) _____

Date/Time of Administration: _____

Authorized User Physician (Sign/Date): _____

CHANGE IN PRESCRIPTION DOSE

☐ Dose differs by more than 20% from written directive, state reason:

_____

_____

Authorized User Physician (Sign/Date): _____

UM RADIATION ONCOLOGY INTERSTITIAL BRACHYTHERAPY TREATMENT
Sr-90 NOVOSTE BETA-CATH WRITTEN DIRECTIVE

Source Train Lengths and # of Dwells for Specific Injury Lengths

a) **5 mm margin± and 5 mm overlap:**

Source Train	Injured Length	Pull Back
40 mm	0 to 30 mm	N/A
60 mm	30.1 to 50 mm	N/A
2 x 40 mm	50.1 to 65 mm	35 mm
3 x 40 mm	65.1 to 100 mm	35 mm each
2 x 60 mm	65.1 to 105 mm	55 mm
3 x 60 mm	105.1 to 160 mm	55 mm each

b) **10 mm margin± and 5 mm overlap (default):**

Source Train	Injured Length	Pull Back
40 mm	0 to 20 mm	N/A
60 mm	20.1 to 40 mm	N/A
2 x 40 mm	40.1 to 55 mm	35 mm
3 x 40 mm	55.1 to 90 mm	35 mm each
2 x 60 mm	55.1 to 95 mm	55 mm
3 x 60 mm	95.1 to 150 mm	55 mm each

±A 5 or 10 mm distal and proximal margin is recommended, however, due to patient anatomy, the distal margin may not be achievable.

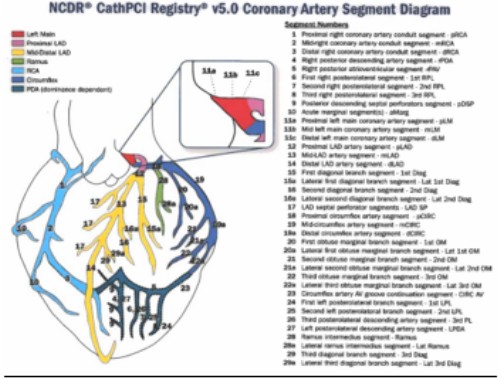
The maximum injury length that can be treated with a given source train can be calculated as:

n x Source Train Length (mm) – Distal Margin (mm) – Proximal Margin (mm) – (n -1) x Overlap (mm)

where n is the number of dwell positions, and overlap is the length of overlap between the dwell positions (2.5 mm minimum and 5 mm recommended).

Similarly, to verify remaining proximal margin with anticipated overlap within the range of 2.5 – 5 mm:

n x Source Train Length (mm) – Injury Length (mm) - Distal Margin (mm)– (n -1) x Anticipated Overlap (mm)



Survey Form

UM RADIATION ONCOLOGY INTRAVASCULAR BRACHYTHERAPY TREATMENT
^{90}Sr NOVOSTE BETA-CATH SURVEY

Radiation Survey Form

Patient's Name: _____ Reg. #: _____

Area of Treatment: _____ Isotope: ^{90}Sr

Date and Time of Treatment: _____ at _____ am/pm

Pre Delivery Survey

Survey meter used: Model & Serial Number: ☐ Fluke V451B, SN 3688

☐ Other: _____

Survey meter battery operational and check source reading verified? Yes No

Exposure Rate: _____ mR/hr (Contact with Transfer Device)

Exposure Rate: _____ mR/hr (Room)

Exposure Rate: _____ mR/hr (1 foot from Patient)

Signature: _____ Date: _____ Time: _____

Post Delivery Survey

Exposure Rate: _____ mR/hr (Contact with Transfer Device)

Exposure Rate*: _____ mR/hr

* Reading includes survey of delivery catheter, fluid collection bag, and the procedure room.

Exposure Rate: _____ mR/hr (1 foot from Patient)

Signature: _____ Date: _____ Time: _____

Patient Name: _____ ***MRN:*** _____

Date of Treatment: _____ ***Source Delivery Device:*** ☐ ***40 mm***

☐ ***60 mm***

1. ***NOTE ABOUT GUIDELINERS: Please note, if a guideliner is needed for catheterization, a 7F guideliner must be used. The Beta-Cath delivery catheter is 6F.***
2. ***Materials and Documentation Required for IVBT Administration:***
   - ❑ Lead Aprons
   - ❑ Emergency equipment (temporary storage container, response kit, and medical physicist kit)
   - ❑ Timer (minimum of 2)
   - ❑ Laser marker (optional)
   - ❑ Documentation, including written directive form
     - ❑ Verify effective dates of the Beta-Cath source on the written directive
   - ❑ Ionization Survey Meter and GM Tube
   - ❑ Cart/table to prepare source transfer device
   - ❑ Novoste B-Rail 3.5F delivery catheter box
   - ❑ Paper tape
   - ❑ Sterile water (minimum 50 cc)
   - ❑ Sterile cup/basin
   - ❑ Sterile towels
   - ❑ Clean gloves - 2 sets for Medical Physicist
   - ❑ Transfer Devices (both 40 and 60 mm)
     - ❑ Measure and record the initial radiation field for Transfer Device using an ionization survey meter.

	40 mm Train	60 mm Train
Exposure Rate (mR/h)		

3. ***Pre-Administration Checks***
   - ❑ Confirm that the Cardiologist, RadOnc, and Medical Physicist have body and ring badges, and that they are worn appropriately.
   - ❑ Perform patient time out – verify patient name and date of birth
   - ❑ Measure and record the initial radiation field for the patient using an ionization survey meter.

Exposure Rate (mR/h)

4. ***Setup of Sterile Field***
   - ❑ Place a sterile drape on the cart/table.
   - ❑ Open β Rail delivery catheter box.
   - ❑ Open the procedure accessory pack and delivery catheter pouch.
   - ❑ Sterile RadOnc will place both items onto sterile field.
   - ❑ Place sterile cup or bowl on the field.
   - ❑ Medical Physicist to fill sterile cup/basin with sterile water.

5. ***Preparation of Delivery Catheter***
   - ❑ RadOnc to fill two 20 mL syringes with sterile water. Tap syringes to remove any air bubbles.
   - ❑ RadOnc attaches one of the 20 mL syringe with sterile water to the blue hub of the Indicator of Source Train Wire which is pre-loaded in the delivery catheter. Holding onto honey dipper, rotate the Indicator of Source Train Wire vertically, apply pressure to the syringe flushing fluid into inner lumen until water is emitted out between the hub and catheter (applying pressure to the syringe for approximately 45 s).
   - ❑ RadOnc to disconnect syringe from Indicator of Source Train Wire.
     - ❑ **NOTE:** If the blue hub separates from the catheter while flushing, fully reinsert Indicator of Source Train Wire back into catheter carefully. The Indicator of Source Train Wire will aid tracking and proper catheter positioning across the interventional injury site by referencing the 40mm or 60mm treatment zones.

6. ***Treatment Plan Preparation***
   - ❑ Based on the vessel diameter and injured length plus margin, the Cardiologist, RadOnc, and Medical Physicist will determine appropriate Radiation Source Train length/Transfer Device and number of stepping positions to use.
   - ❑ RadOnc and Medical Physicist will discuss target site, vessel diameter, and develop a treatment plan.
   - ❑ Medical Physicist to capture oral directive on written directive form
   - ❑ Medical Physicist enters treatment time for administration into primary and secondary timer.
     - ❑ If more than one dwell position is planned, Medical Physicist to enter treatment time for administration on a second set of timers.
     - ❑ RadOnc visually verifies treatment times entered on timers.

7. ***Preparation of Transfer Device***
   - ❑ RadOnc at sterile field
   - ❑ Medical Physicist to set appropriate transfer device on non-sterile cart and open lid
   - ❑ Medical Physicist to remove the red and white port covers from the appropriate Transfer Device.
   - ❑ Medical Physicist to hold device vertical and power on the Transfer Device. Verify green "In" light illuminates and solenoid clicks (this should occur once).

Quality Assurance

- First use and biannually
  - Source assay
  - Leak test
  - Source uniformity

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Chakri & Thomadsen, Med Phys, 29(12); 2002: 2850 – 2860
Chiu-Tsao *et al.*, Med Phys, 34(11); 2007: 4126 - 4157

Quality Assurance

- Day of use
  - Survey meter check – battery check and functionality using a check source
  - Transfer device – battery check and functionality of device, including indicator lights
  - Verification of patient identity using at least two methods
  - Transfer device selection - review injury length, reference vessel diameter, and margins
  - Verify time entry on primary and secondary stopwatches
  - Verify correct transfer device selected – independent check

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Quality Assurance

- Day of use
  - Delivery catheter – clearance using the indicator of source train
  - Source positioning – using indicator of source train and with source during txmt under fluoros (~ every 30 s)
  - Source retraction at completion of txmt – visual and based on survey reading
  - Review of written directive

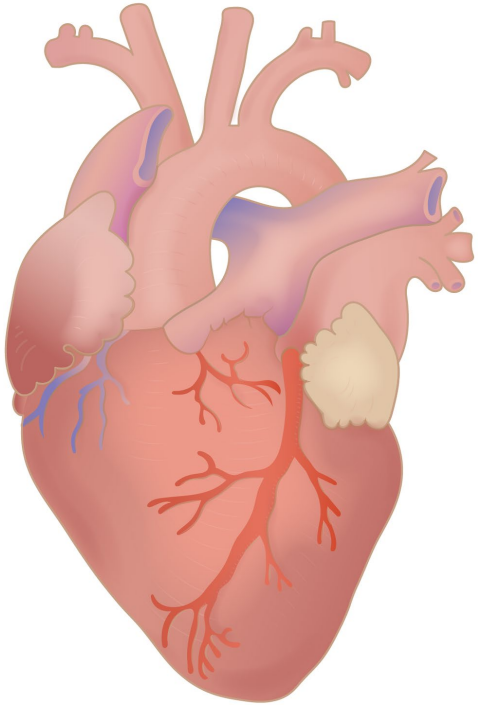
- Chart/plan audit
- Routine program reviews and quality improvement initiatives

Nath *et al.*, Med Phys, 26(2); 1999: 119 – 152
Chakri & Thomadsen, Med Phys, 29(12); 2002: 2850 – 2860
Chiu-Tsao *et al.*, Med Phys, 34(11); 2007: 4126 - 4157

Summary

- There are a subset of patients who experience in-stent restenosis following repeat stenting with drug eluding stents.
- These failures have resulted in renewed interest and the re-emergence of intravascular brachytherapy.
- To initiate a IVBT program, clinics need to submit and receive approval for a new or amended byproduct material license, and commission their program.
- A robust quality assurance program and routine reviews and program improvements will contribute to a success IVBT program.

Thank



you!