

In Vivo Brachytherapy (IVBT)

IntraVascular Brachytherapy

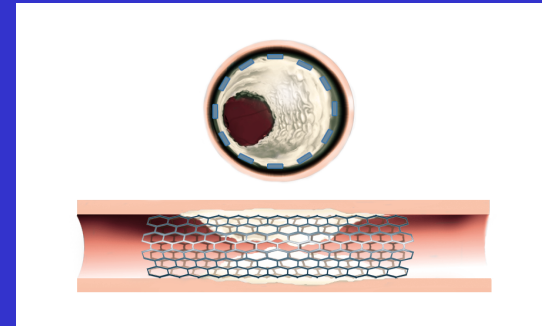
What we will Cover Today

- **Rationale for IVBT**
- **Contraindications**
- **How it works**
- **What is the best Isotope?**
- **Time Considerations**
- **Logistics Considerations**
- **Team Members**
- **Team Member Roles and Responsibilities**

What we will Cover Today

- **Institutional Responsibilities**
- **Guidant System (recalled 2004)**
- **Novoste System**
- **Cordis Systems**
- **Licensing**
- **What Do I Inspect?**
- **Conclusions**
- **Questions and Answers**

Why Intravascular Radiotherapy for Restenosis?



Over 1.4 million percutaneous coronary interventions will be completed worldwide each year, of which ~ 80% will involve a new stent.

Over 200,000 patients will develop recurrent symptoms due to in-stent restenosis worldwide this year.

Intravascular Radiotherapy Contraindications

- unprotected left main disease (>50% narrowing)
- patients in whom antiplatelet and/or anticoagulant therapy is contraindicated

IVB Radiation Works



Pre-PTCA

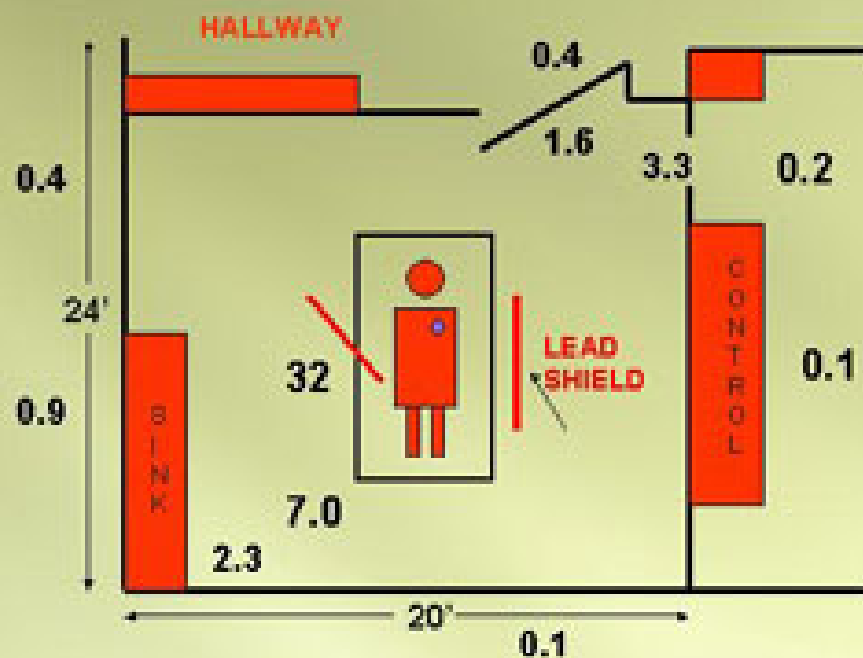


Post-PTCA/Radiotherapy



Six Months Post-PTCA/Radiotherapy

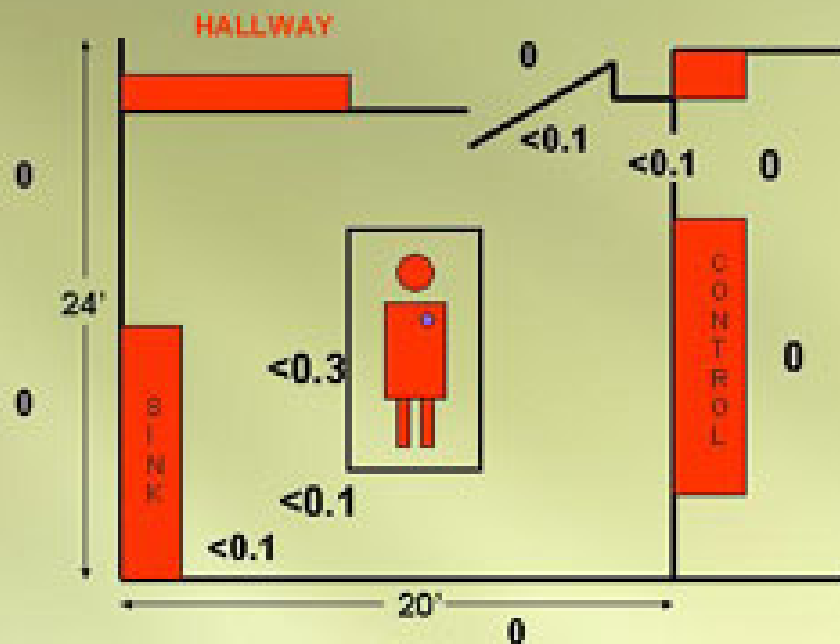
Exposure (mR/hr) from 100 mCi of ^{192}Ir (*SCRIPPS Trial*)



Source: S. Jani

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Exposure (mR/hr) from ^{32}P (beta)* (PREVENT Trial**)



* 150mCi Source - **Results of trial have not been published.

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Time Considerations

Gamma

≥ 20 minutes

^{32}P

≤ 10 minutes

All

Pre-procedure: 20 - 30 min

Post-procedure: 10 - 15 min

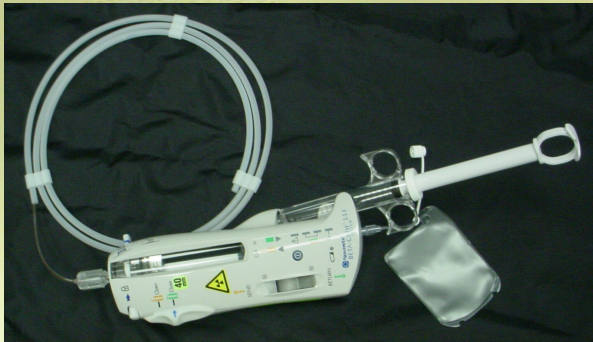


Source: Clinical Trials in Radiation Therapy for Restenosis: Past, Present and Future, Ron Waksman, Vascular Radiotherapy Monitor, Volume 1, No 1, 1998, pages 10 - 18.

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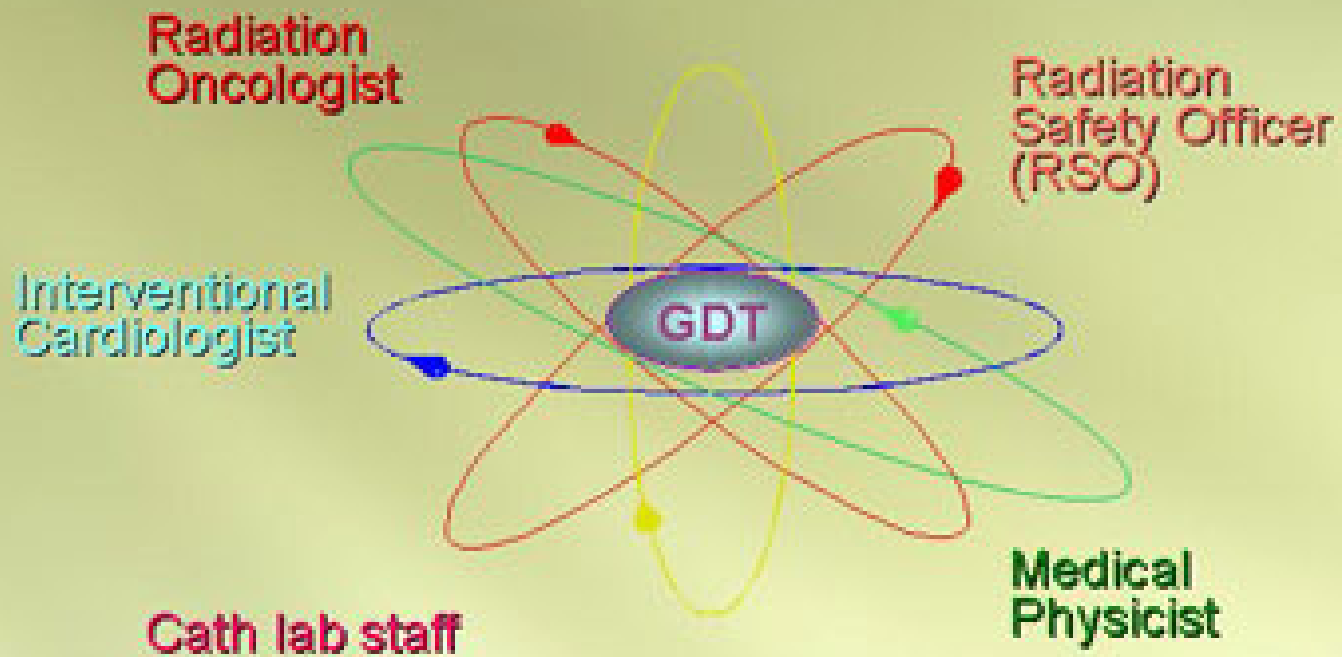
Logistical Considerations

- Location of cath lab vs. oncology dept.
- Location of Source Delivery Unit
- Integration of SDU into lab



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Radiotherapy Team Members



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Roles and Responsibilities

Interventional Cardiologist



- **Prior to Procedure:**
 - Patient Consent for Intervention
- **Performance of Procedure:**
 - Perform Intervention
 - Determine Vessel Sizing
 - Determine Treatment Area
 - Monitor Patient
- **Post Procedure:**
 - Remove Catheter

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Roles and Responsibilities

Radiation Oncologist



- **Prior to Procedure:**
 - Patient Consent for Radiation Treatment
 - Patient Risk
- **Performance of Procedure:**
 - Prescribe Treatment
 - Determine Treatment Area
 - Position Source
- **Post Procedure:**
 - Sign Prescription

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Roles and Responsibilities

RSO



- Prior to System Delivery
 - Licensing Application
 - Radiation Safety Program
- Source Receipt and Return

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Roles and Responsibilities

RSO/Medical Physicist



- Performance of Procedure:
 - Survey When Appropriate
 - Monitor Dwell Time
- Post to Procedure:
 - Storage of SDU
 - Survey Patient
 - Survey Catheter
 - Survey Lab

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Roles and Responsibilities

Cath Lab Staff



- **Prior to Procedure:**
 - Coordinate schedules
 - Prepare patient for procedure
- **Performing the Procedure:**
 - Prepare Centering Catheter
 - Assist Interventional Cardiologist with procedure

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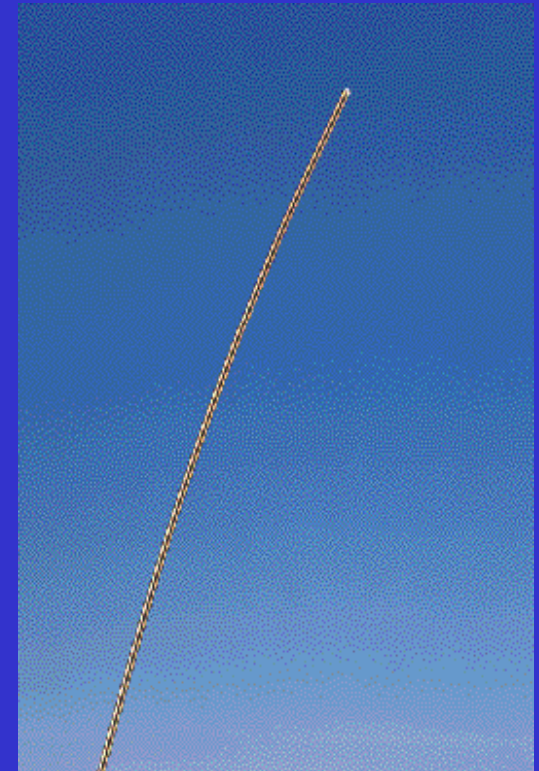
Institution Responsibilities



- License compliance
- Training of Authorized Users and ancillary personnel
- Designation of qualified RSO and Authorized Users
- Payment of fees or fines associated with license amendment and license non-compliance
- Maintenance of records including patient agreement, training and patient records

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Guidant System



Automated Source Delivery Unit



- Touch-screen operation
- Software automates all dosimetry functions
- Automated Source Wire delivery and retraction
- Shields and stores the source wire
- Multiple safety features

Guidant beta Source Delivery Unit

Cartridge Exchange Procedures

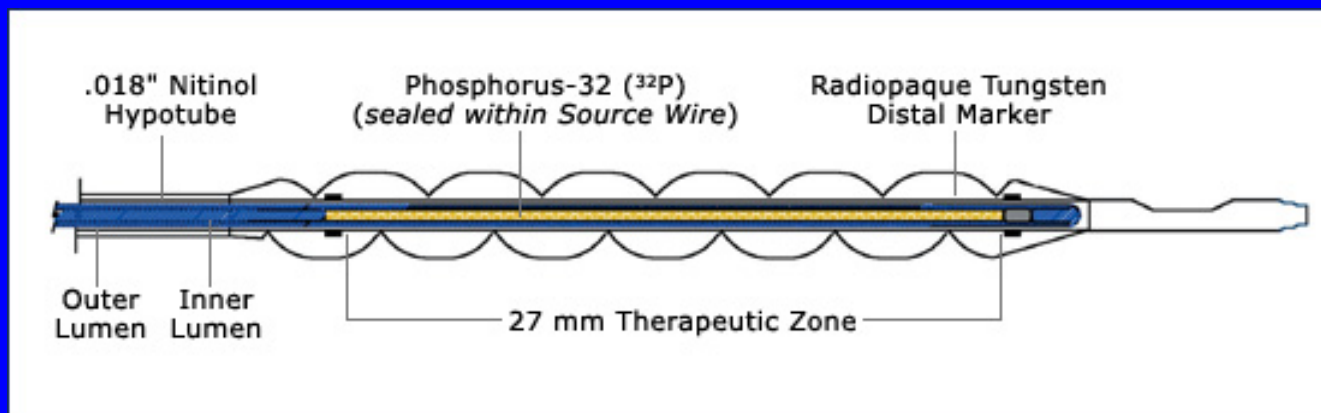
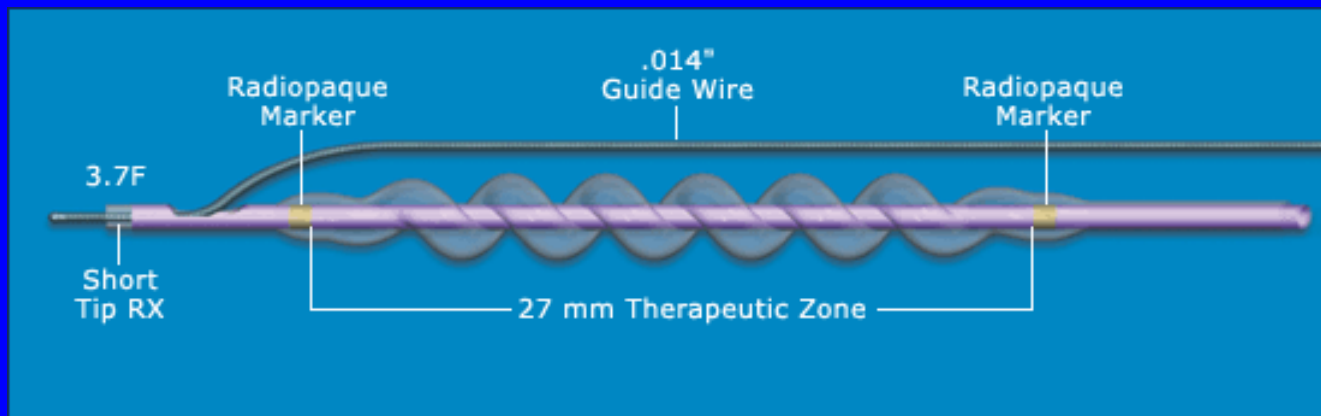


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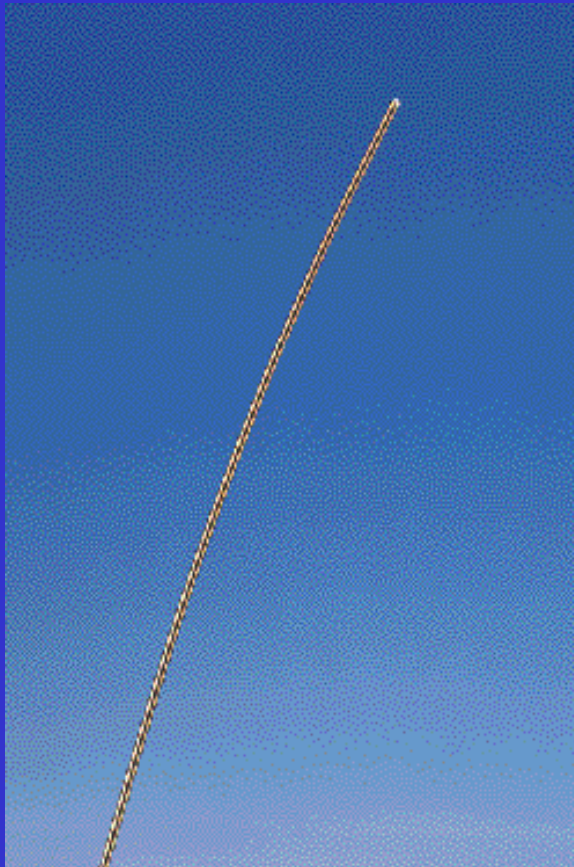
Galileo Screen



Centering Catheter and Source Wire

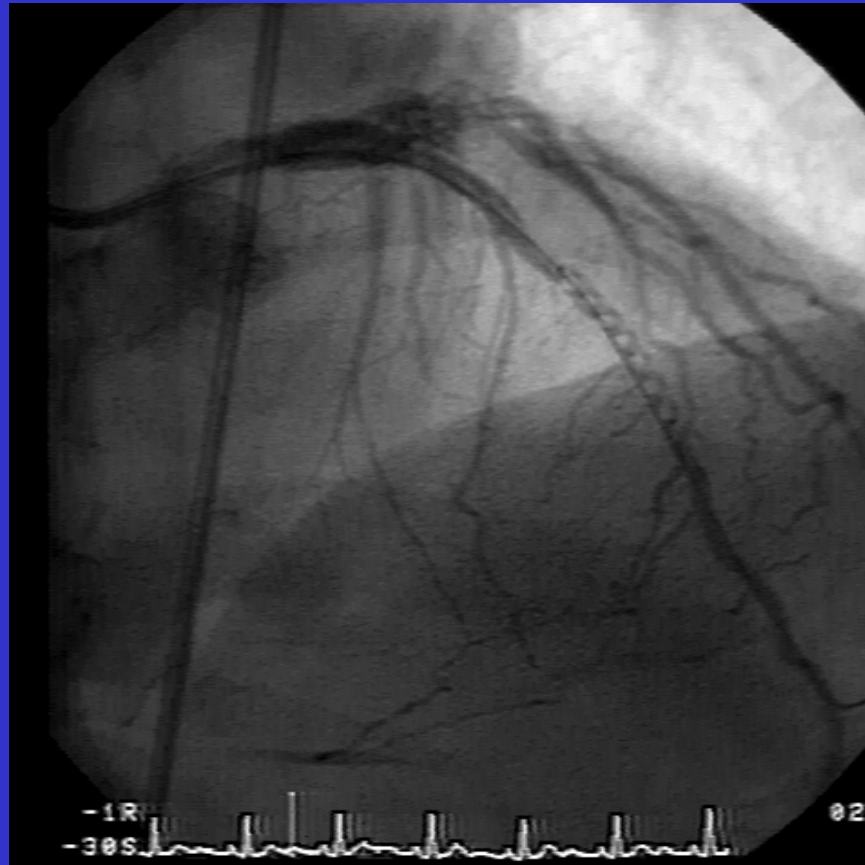


Source Wire



- Solid-form, beta isotope (Phosphorus-32) sealed within distal tip
- .018 inch Nitinol hypotube
- Travels through dedicated, dead-end catheter lumen
- Re-usable

Centering Catheter - In Use

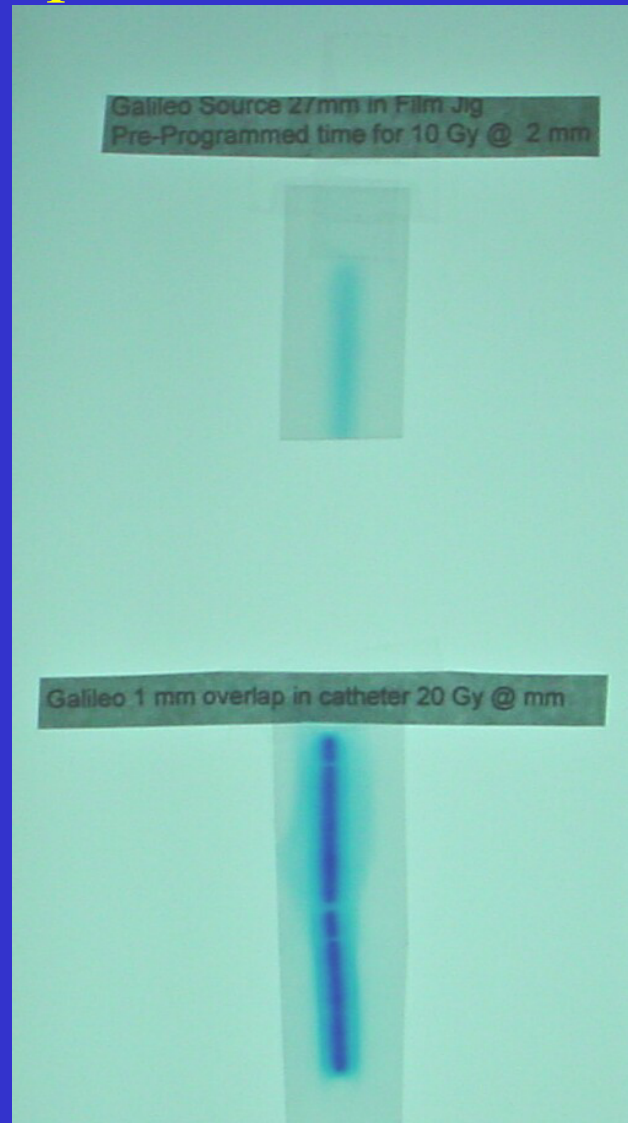


Unretouched image from PREVENT

Dosimetry Galileo

- Dose prescription point is fixed 20 Gy @ 1mm beyond the average reference lumen diameter.
- Reference Vessel Diameter (RVD) - Disease free reference segment to which the minimal lumen diameter of the diseased segment can be compared.
- Minimum Lumen Diameter (MLD) - Angiographic core lab measurement of the most narrow point within the analysis segment measured in mm.

Guidant Autoradiography in film phantom, catheter taped to film

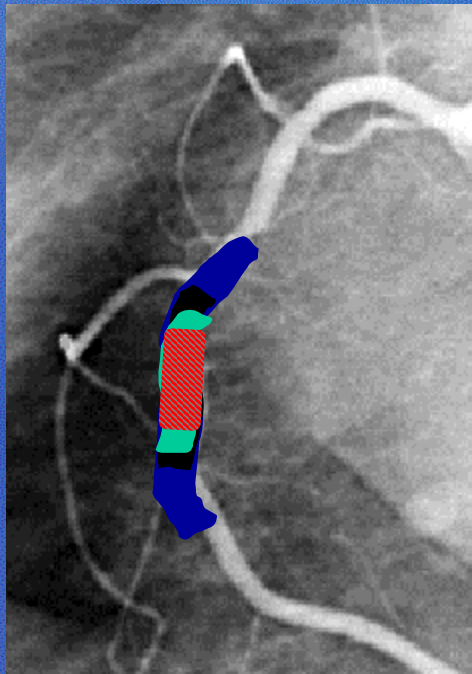


Guidant INHIBIT Trial

Key Results

- 53% reduction of MACE with TLR versus the control group.
- 70% reduction of recurrent in-stent restenosis versus the control group.
- Effective in treating long lesions (≤ 47 mm) and small vessels (2.4 mm - 3.7 mm).

QCA Methods



Stent Segment
Length = 24.5 mm



Injured Segment
Length = 29.0 mm

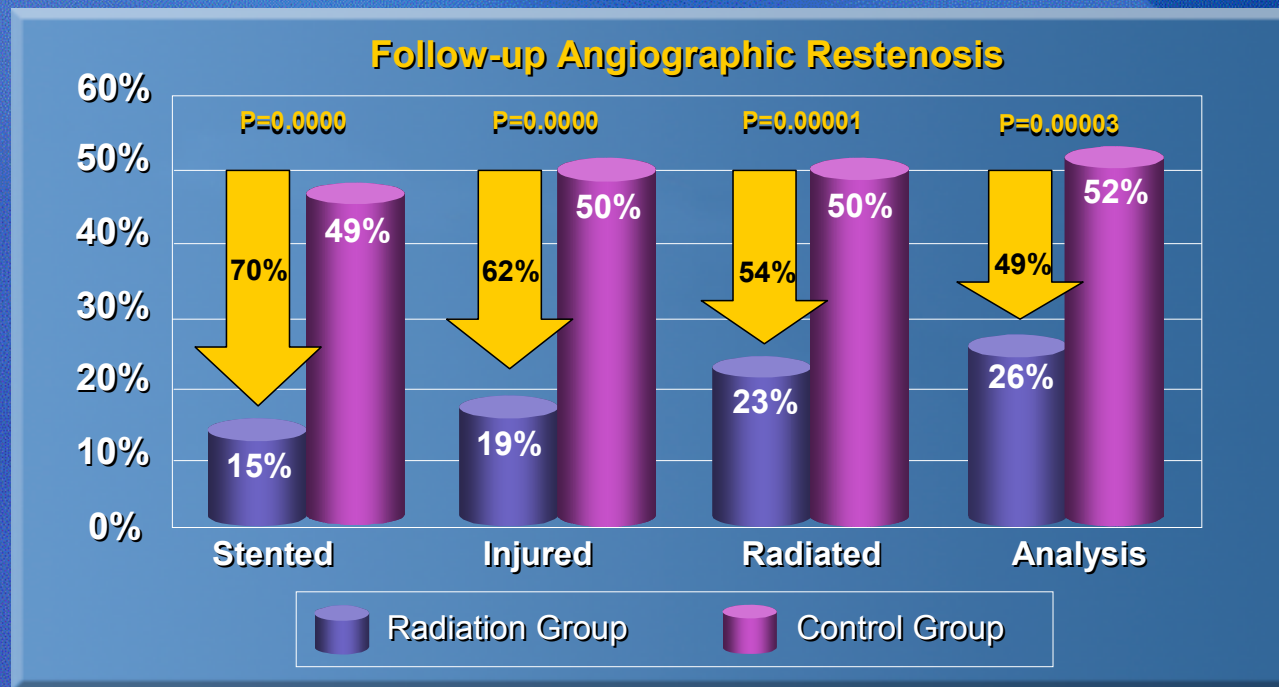


Radiated Segment
Length = 35.6 mm



Analysis Segment
Length = 45.8 mm

Demonstrated Efficacy



Medical Physicist's Emergency Duty: Guidant

Emergency Response Procedures

Medical Physicist



- Note the time this part of the procedure was begun
- Remove Cartridge from SDU and shield
- Press Catheter eject button
- Remove Centering Catheter key from Centering Catheter Port
- Slide Centering catheter along wire

Medical Physicist's Emergency Duty: Guidant

Emergency Response Procedures

Medical Physicist

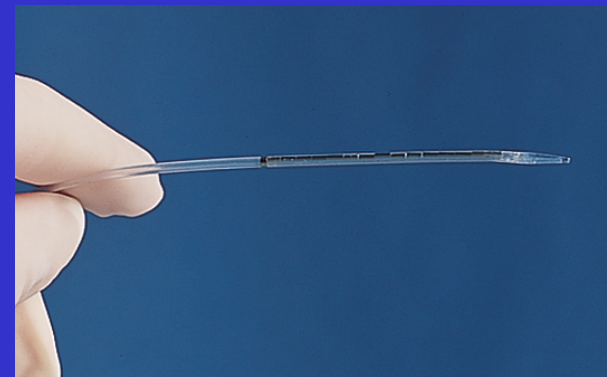


- Cut Active wire at Catheter Key Port using Emergency Wire Cutter
- Place cut wire into Emergency Safe using Emergency Tongs
- Note the time the Centering Catheter was safely shielded
- Perform Radiation survey

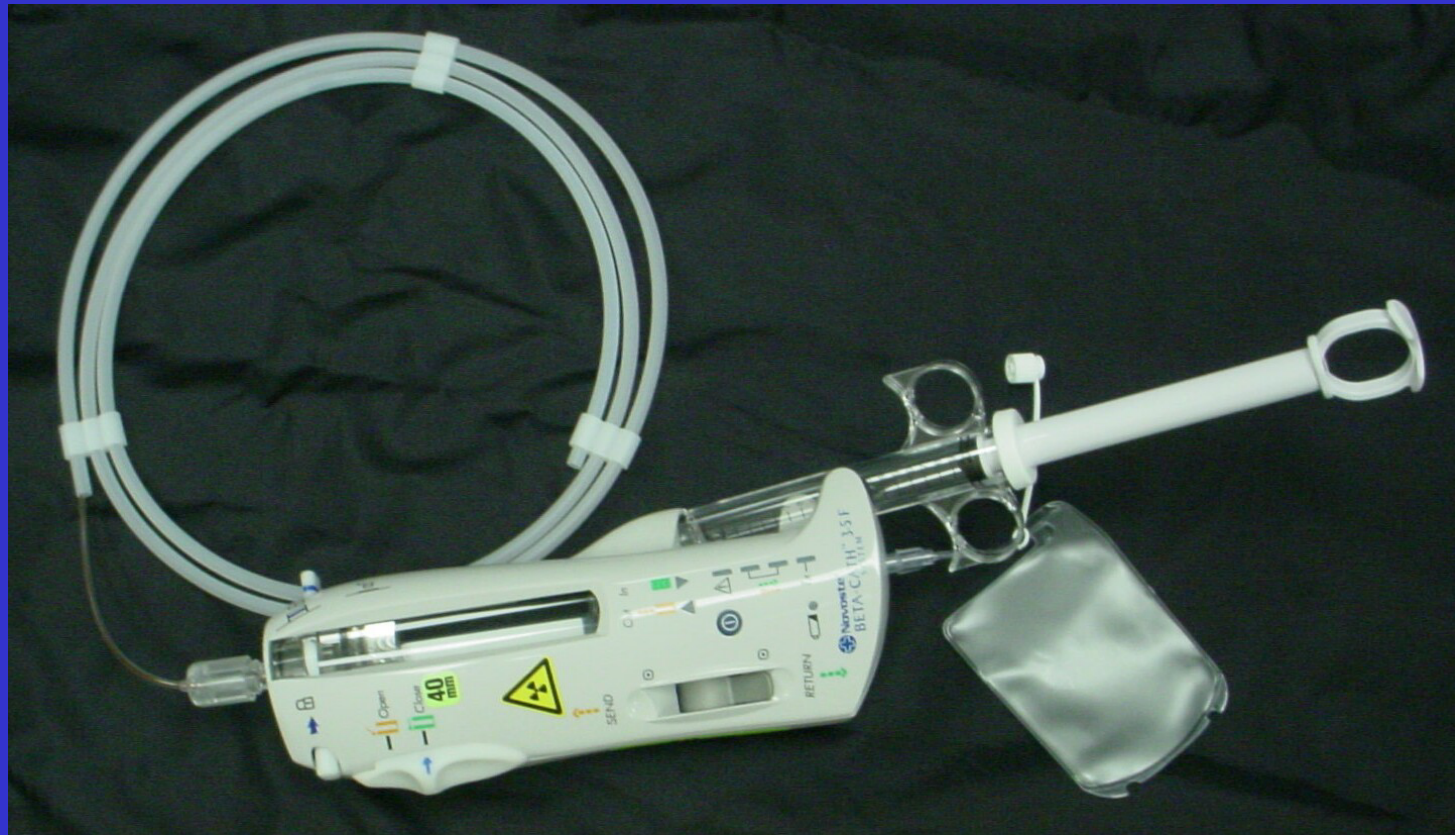
Guidant Emergency Response Kit



Novoste System



Novoste 40 mm 5 Fr. Device



Novoste Equipment



Dosimetry Novoste: Rx

Recommended dose Prescribed
2 mm from center of source train

Vessel Diameter (mm)

≥ 2.70 to < 3.35

18.4 Gy

> 3.35 to ≤ 4.00

23.0 Gy

Novoste beta sources in stent



Treating Longer Injured Segments

Galileo - stepping source train, 3 positions

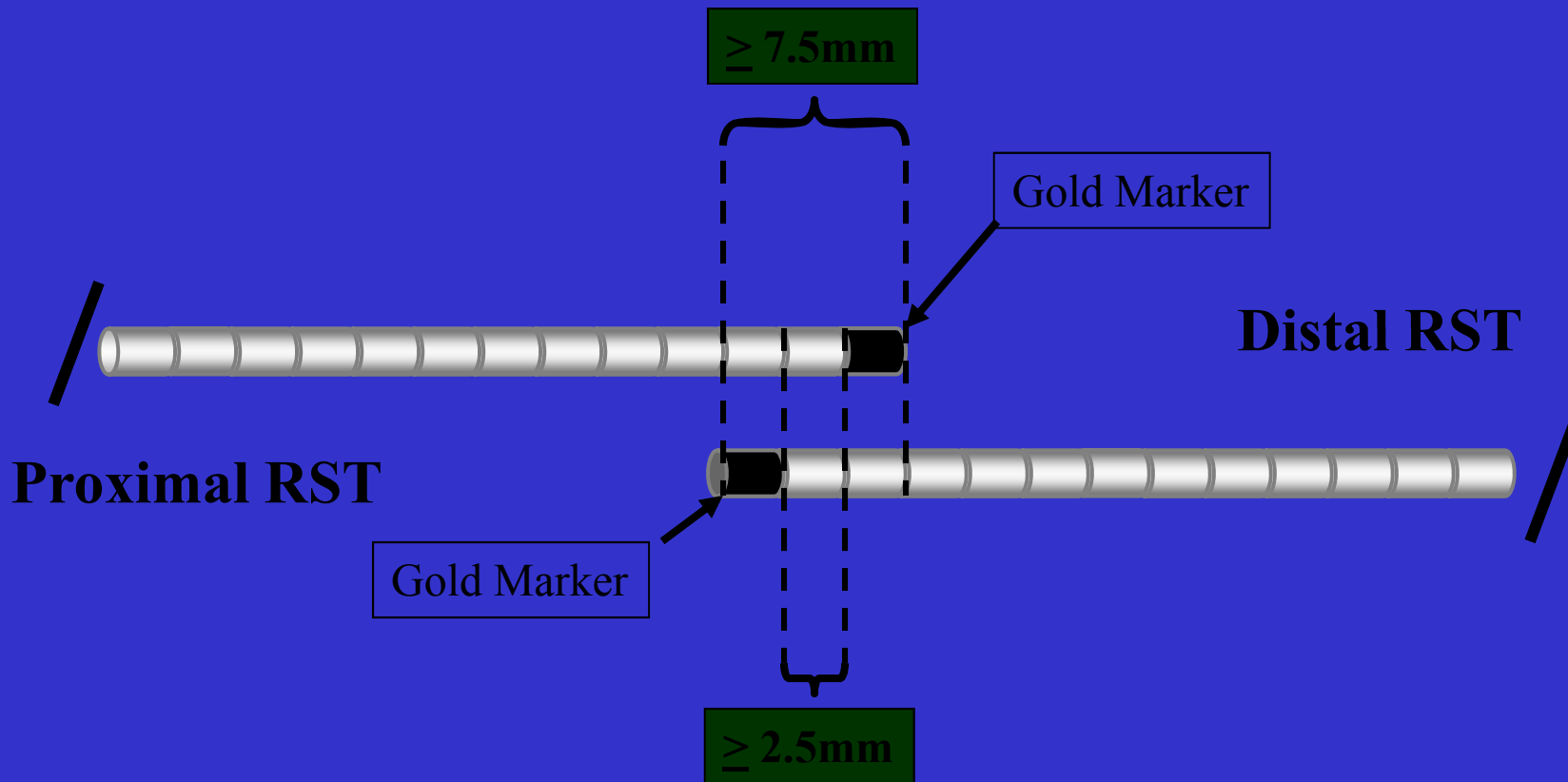
Novoste - Sequential positioning or
“pullback” technique

These images are for 30 and 40 mm

Novoste source trains, 60 mm

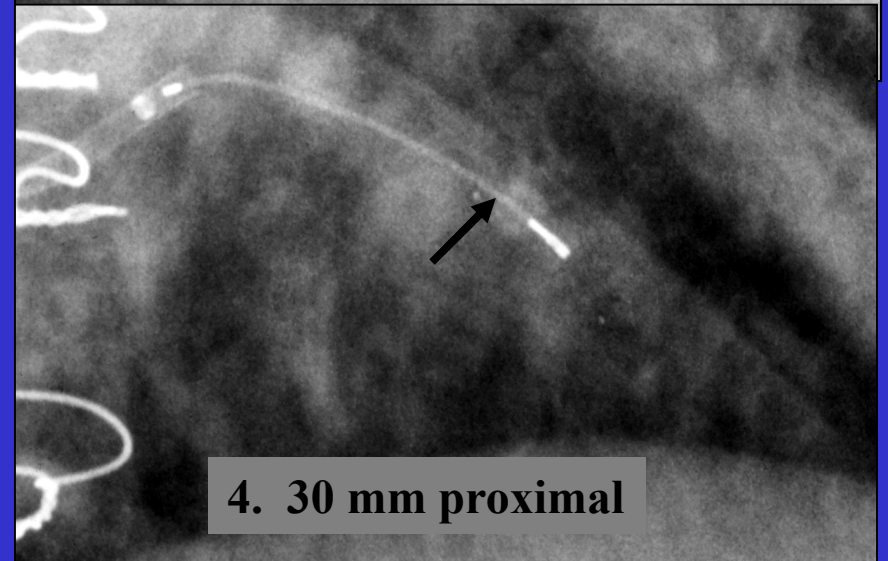
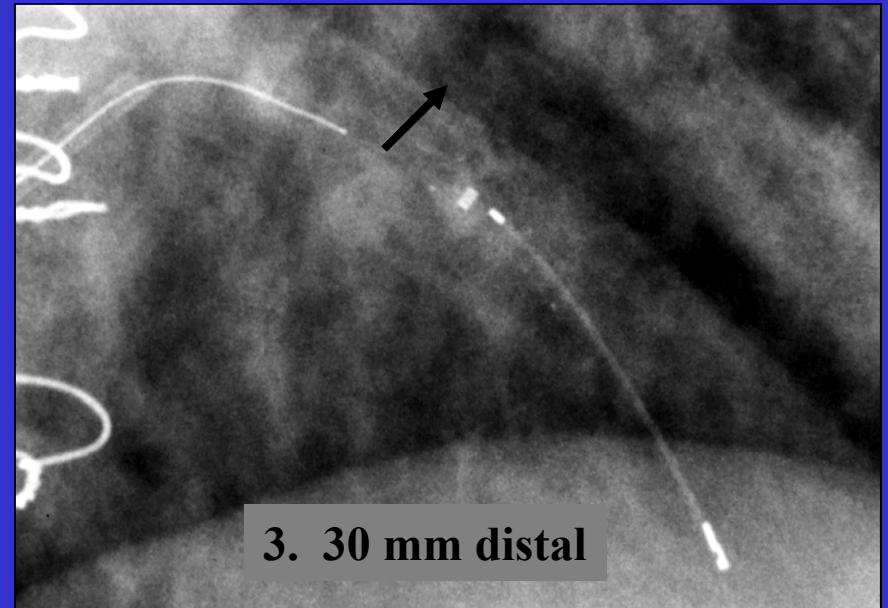
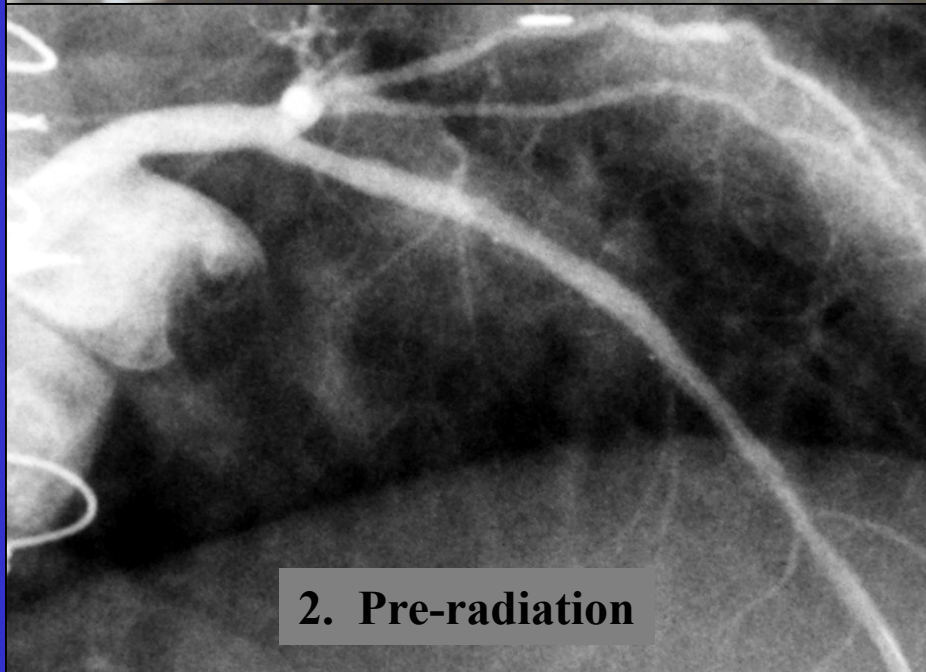
Implement VBT

Sequential Positioning Technique: “Pullback” of Radiation Source



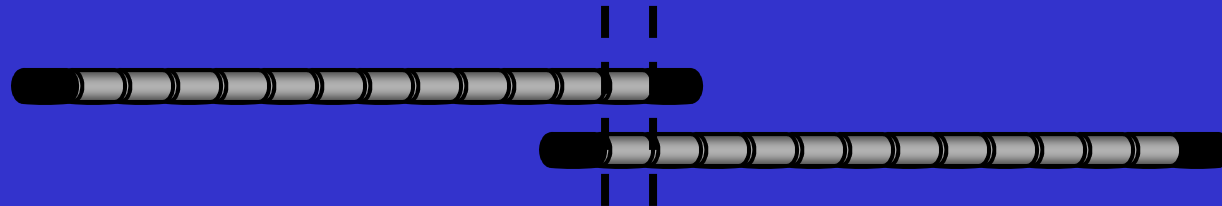
Implement VBT

Sequential Positioning Technique: “Pullback” of Radiation Source

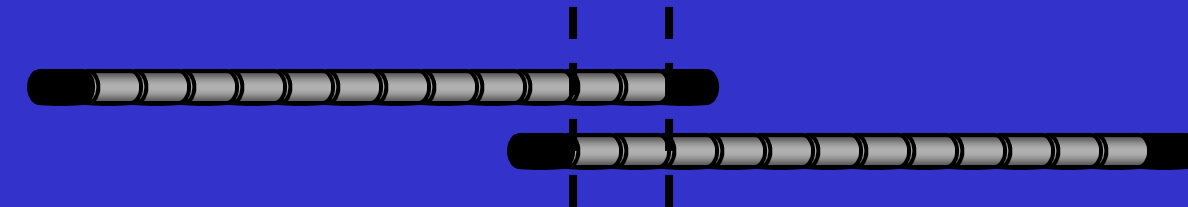


Dosimetric Analysis of Sequential Positioning Technique

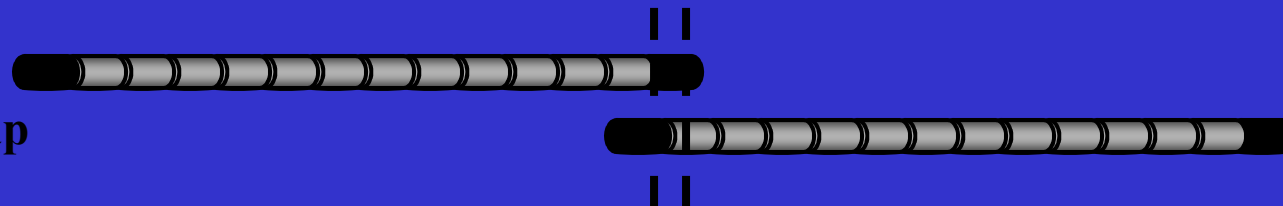
One source overlap



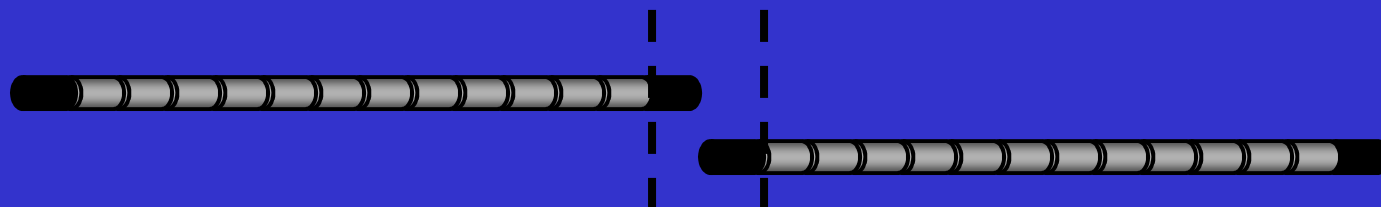
Two source overlap



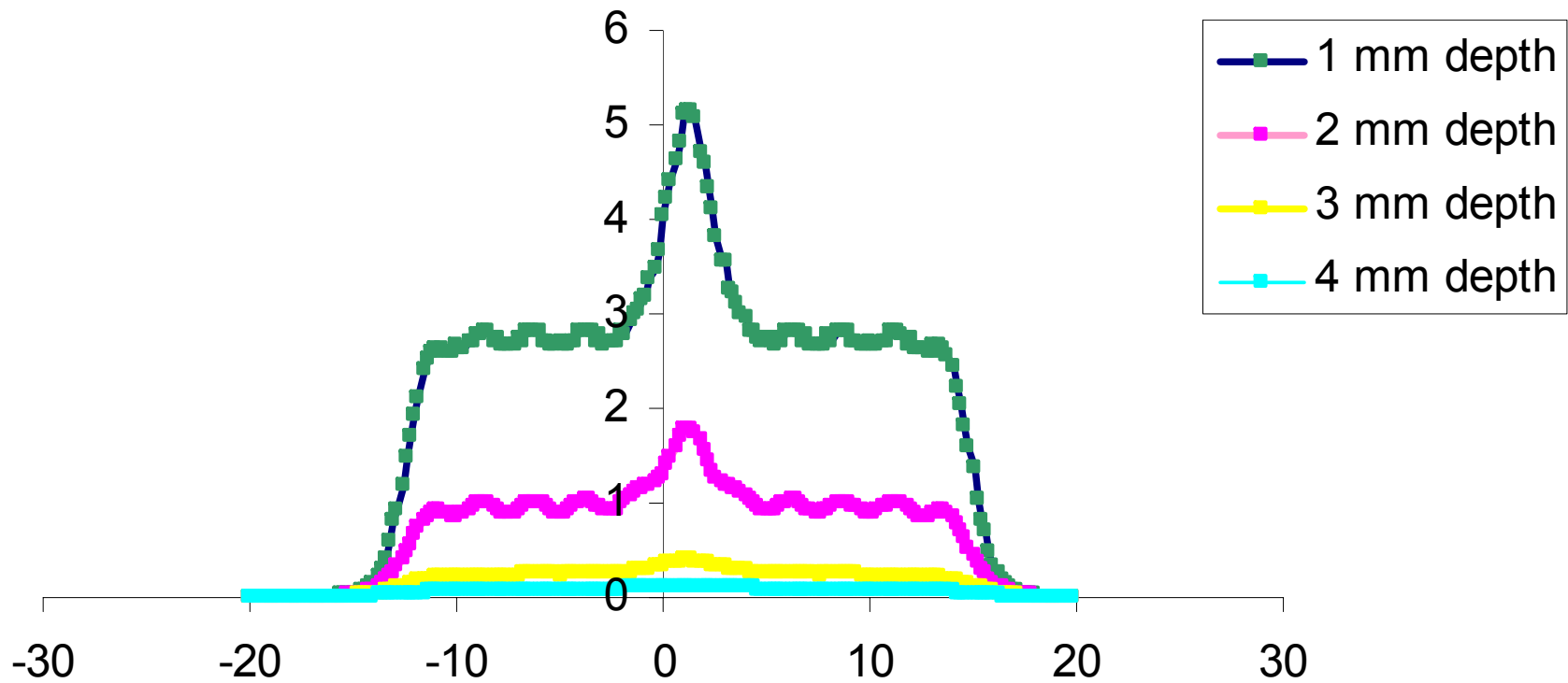
One-half source gap



Two source gap

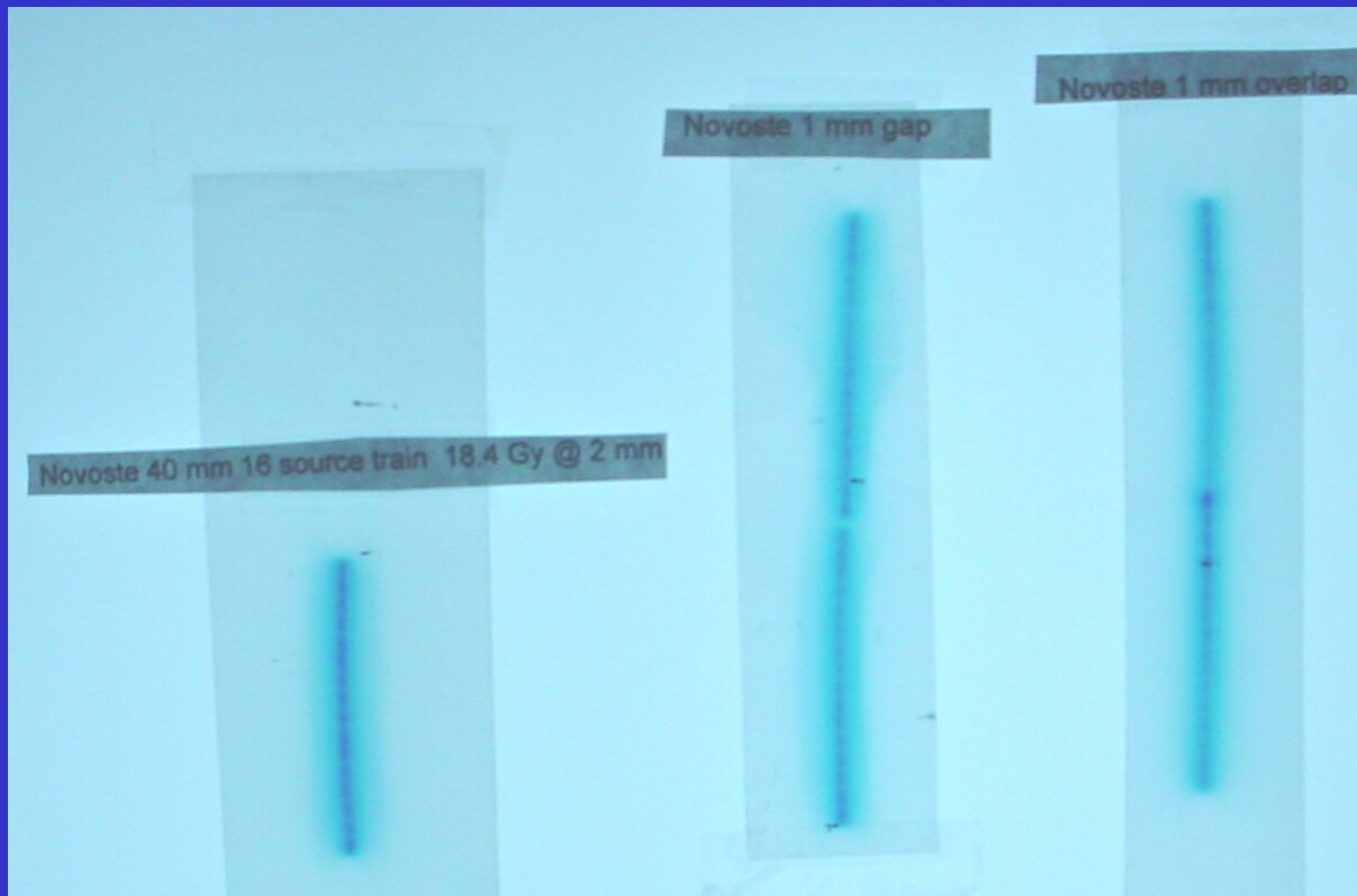


Dosimetry: One Source Overlap

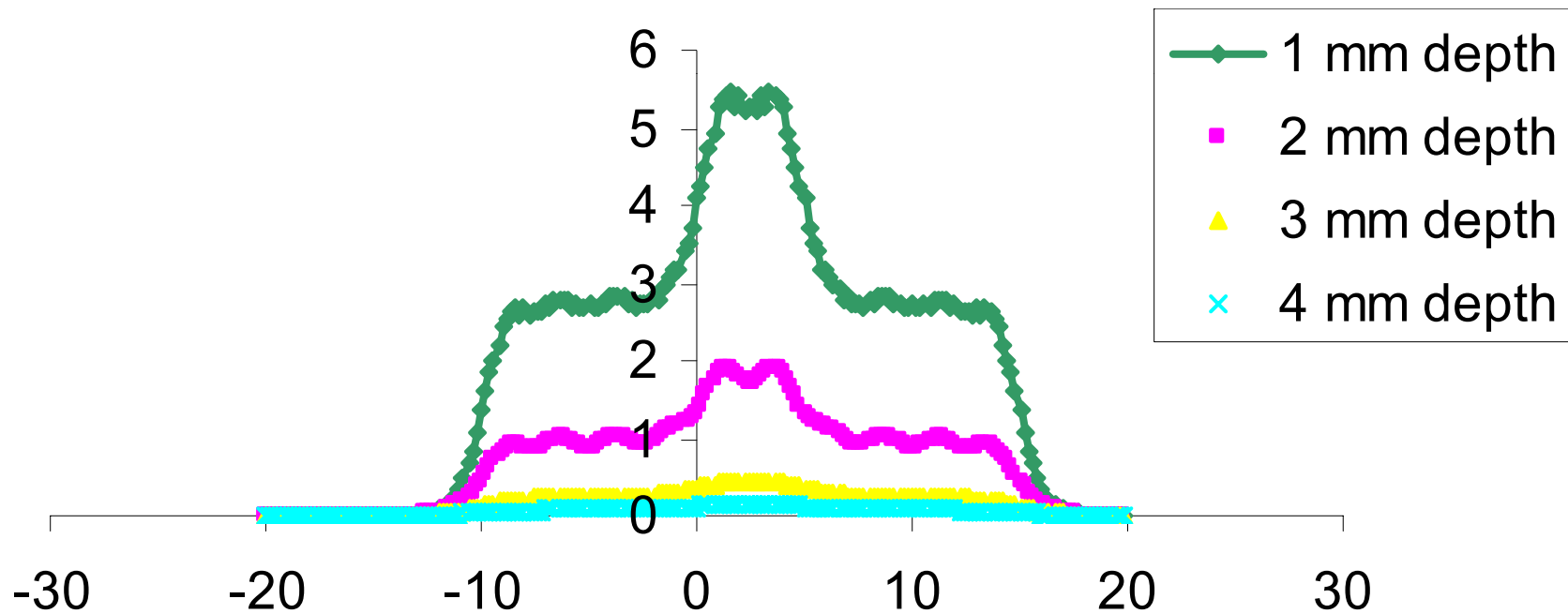


Novoste Autoradiography

40 mm source train, 1 mm gap, 2 mm overlap

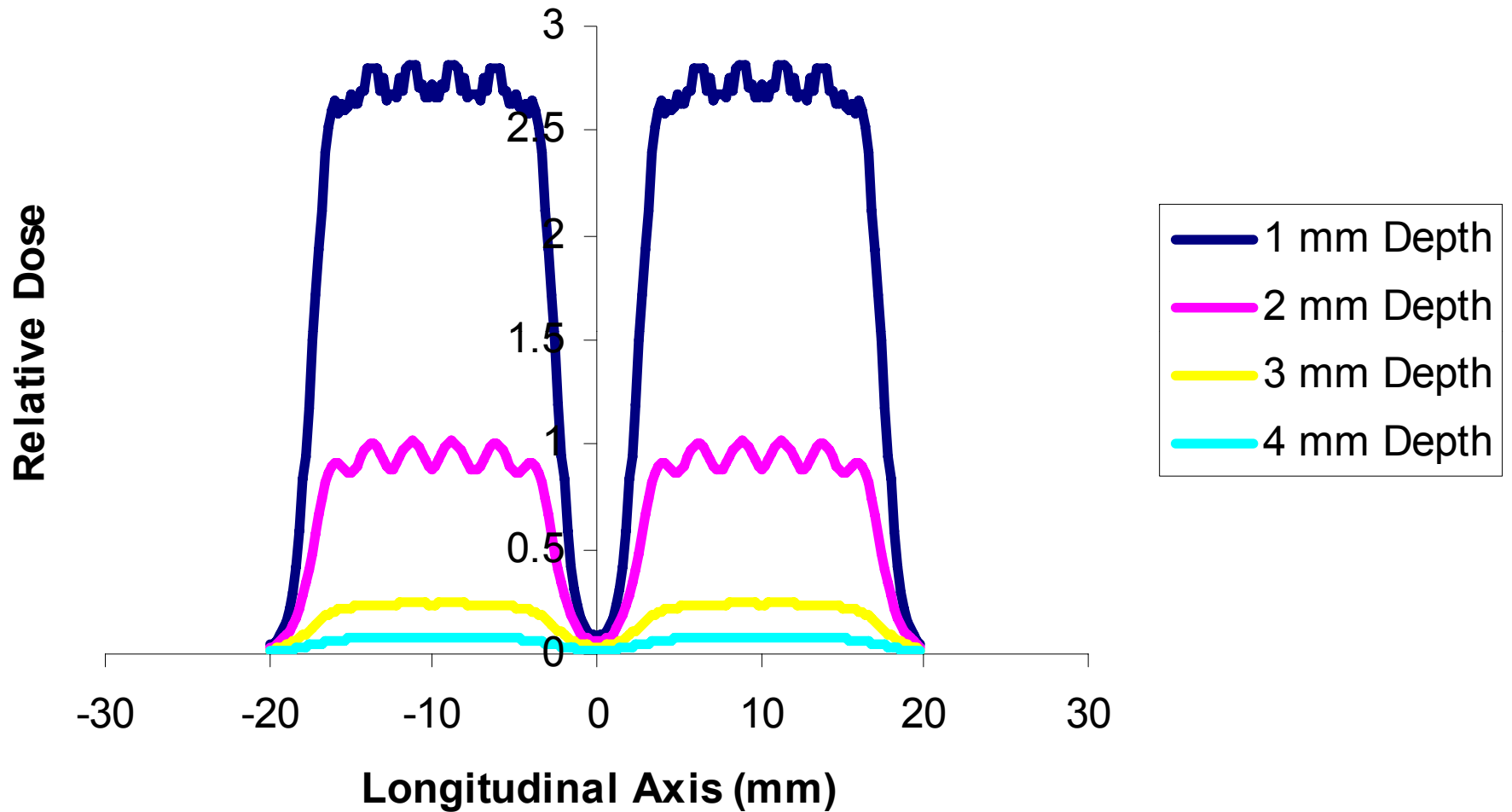


Novoste Dosimetry: Two Source Overlap



Implement VBT

Dosimetry: Two Source Gap



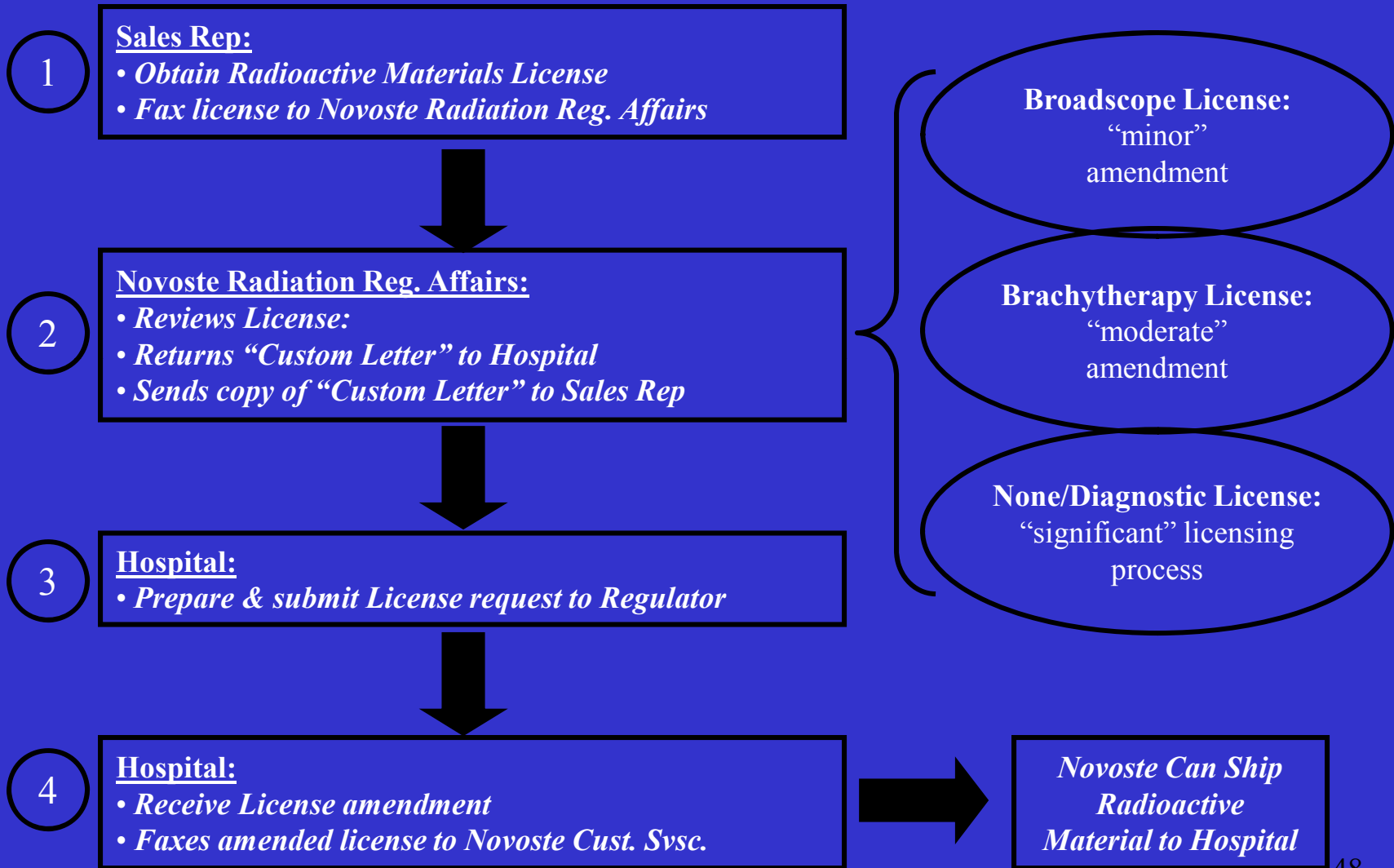
Other IVB Systems

- **Radiance RDX** system uses a low activity (25 mCi) P-32 tri-layered sealed source to treat vessels of various diameters and various lengths.
 - Dwell time is pre-calculated and printed on a label.
 - Manual system is a blood flow restrictor must treat cyclically (available in Europe, Endologix, Inc.; experimental in USA)
- **Cordis Checkmate** system uses Ir-192 with various seed numbers (6,10,14,18 and 22) and various treatment lengths (23,29,55,71 and 87 mm).
 - manual non-centering device, 3-7 French catheters IVUS based and fixed dosimetry
 - Requires room shielding, the activity is kept less than 0.5 Ci
 - Treatment time high, about 15-20 minutes.

Some RAM Licensing Comments

- Medical Physicist works with Hospital Radiation Safety Officer to obtain license
- Either IVBT done in an “Agreement State” or under Nuclear Regulatory Commission
- FDA approval for source and delivery system mandatory - otherwise clinical trial and IRB approval necessary
- Most companies will work with the licensee

Radiation License Amendment Process



What Do I Inspect?

- Licensing Records, Designated Authorized User
- Personnel Training Records
- RAM Receipt Logs, Wipe tests
- 6 month Leak Tests, Leak Test Procedure
- Daily QA Program, Daily QA records
- TX Records, Written Directive, Post TX Survey
- Return Shipping Records
- Emergency Plan: Program, Equipment

Conclusions

- IVBT is a valuable tool for treatment of in stent restenosis
- Authorized Medical Physicist is an important member of IVBT team
- AMP will aid in technical delivery of radiation
- AMP will advise for unusual presentation or technique of delivery (“pullbacks, etc.)
- Drug coated stents are competition, but when failure occurs, IVBT is still a viable treatment