Self-Contained Blood/Biological Irradiator (SCBI) using Flat Panel X-ray Sources

CIRMS Meeting
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Austin, TX

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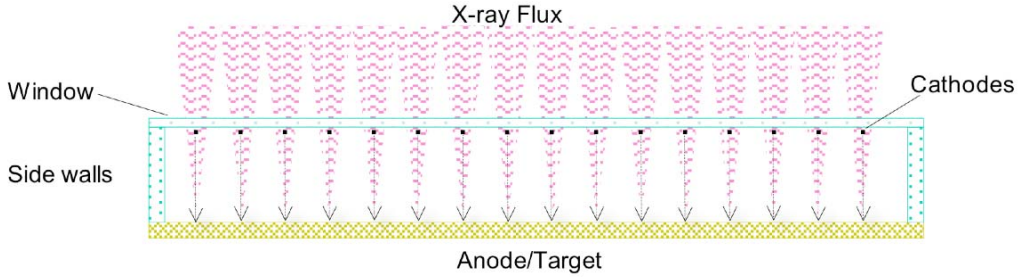
Background to FPXS

- **X-ray/UV-C Source for Biohazard Decontamination**
  - AFRL SBIR, 2004-2007
  - combined source - target anthrax spores
  - background in field emission displays - cold cathode arrays
    - arrays over X-ray target - *reflective* X-ray source
    - arrays over phosphor - cathodoluminescent UV-C

- **Flat Panel X-ray Source**
  - NIST ATP project, 2007 - 2010
  - manufacturing systems and processes
    - materials systems for modules
    - process tools for cathode thin films
    - cathode array fabrication processes
    - driver circuits, on-board HV amplifiers



- **General Characteristics**
  - same physics as a tube, change the architecture
  - *cathode arrays on the exit window*
  - X-rays up from target, out window
  - less heel effect, > 3X power efficiency
  - easy to cool anode from back
  - can make in various sizes

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Span Project

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- **Three-year project to develop, qualify, approve and deploy SCBI**
- **Team: Stellarray, Texas A & M sterilization research center, Red Cross, beta test sites**
- **Main tasks - GVHD irradiator deployment:**
  - Bench-level irradiator: large panels, lifetime tests, sealed panels
  - Irradiator prototype: full-scale operational, 100 kV operation, then 150 kV
  - Testing & qualification: blood irradiation efficacy, platelet life extension
  - FDA approvals
  - Beta testing at blood banks & hospitals, replacement of ^{137}Cs units
- **Platelet shelf-life extension study:**
  - Current regulations allow platelets to be stored for up to 5 days
  - Wastage rates of platelets can be over 25%
  - Limited shelf-life due to increased bacterial contamination
  - Can ionizing radiation extend platelet shelf-life?
  - Trade-off for dose?: kill/inactivate bacterial pathogens before compromise of blood components
- **Dose Comparison Review:**
  - Prior studies of effects of irradiation on blood mainly 662 keV ^{137}Cs gamma rays or ^{60}Co
  - Limited literature low energy X-ray radiation on blood
  - Review comparison of X-rays with gamma rays

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Blood Irradiation

- Main use: inactivate leukocytes to prevent TA-GVHD
  - gruesome, usually fatal condition; irradiation indicated in 10% of transfusions in U.S.
  - ionizing irradiation only method approved by FDA
  - standard: 25 Gy dose to mid-plane; at least 15 Gy, no more than 50 Gy
- Blood irradiation at blood banks and hospitals
- 1,350 “self-contained” (isotope) irradiators in U.S. now
  - 650 used for TA-GVHD, another 100 X-ray tube irradiators
  - over 5,000 users of irradiated blood at hospitals, cancer centers, trauma centers
  - most users have to buy irradiated blood
  - 8 Medicare/Medicaid codes for irradiated blood
  - irradiation cost $55/unit (bag) + transportation
- 23 Mn transfusions in U.S.
  - $175 Mn/year in irradiation service
  - potential for much more
  - Japan - all blood irradiated
- Potential for more irradiators
- Other uses: platelet shelf life extension, implants, other sterilization

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Current Irradiators

- Most use ^{137}Cs isotope
  - 30 yr half life, lower energy than ^{60}Co
  - lead shielding (1 ton)
  - load 1 - 8 bags in canister, rotate 2 - 16 min
- ^{137}Cs a major security concern
  - National Academy of Sciences report, Feb 2008
  - high security and reporting costs
  - blood banks with truck bomb barriers
- X-ray tube models
  - need high power (160 kV) CT tubes
  - external cooling systems, 220V
  - reliability issues
- Both expensive
- Customers motivated for alternative

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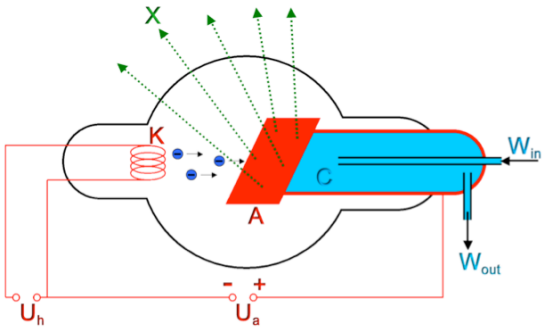
Sources Now

- **^{137}Cs problems**
- **So why haven't X-ray tubes taken over?**
  - *They weren't made for the job*
- **Point source of radiation**
  - single cathode shoots an e-beam into target
  - most energy converted to heat
  - heel effect - only fraction of X-ray flux gets out
  - and then, spread the X-ray flux from 1 mm^2 spot
  - four 400 ml bags = 62,500 mm^2
  - need a powerful tube and more powerful cooling system
  - low lifetime
- **X-ray tube irradiators use two CT-grade tubes**
  - expensive
  - designed to be pulsed and operated briefly
  - not meant for minutes of irradiation
  - cooling system, other failures



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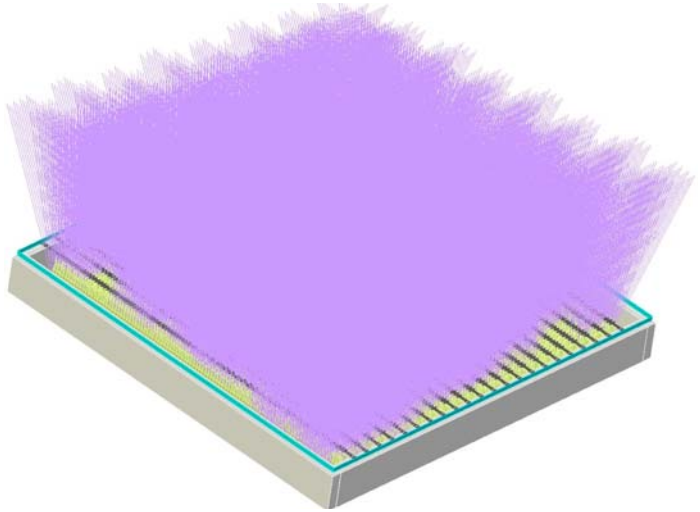
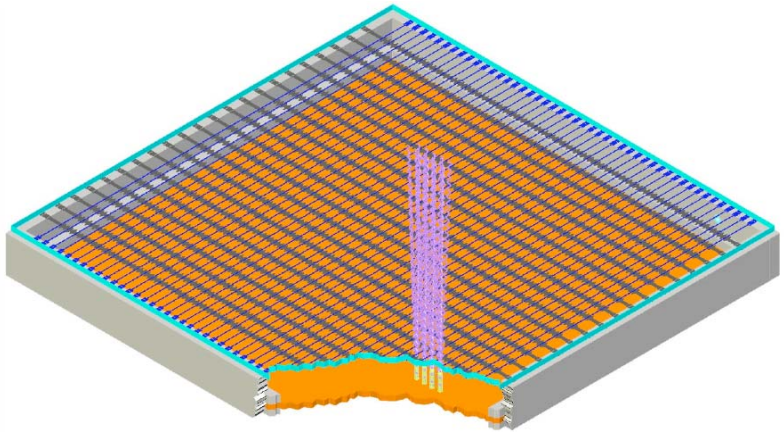
Plain & Pixilated

- **Plain FPXS**
  - whole cathode array on
  - can use hot filament or cold cathode arrays
  - large panels or groups of panels
  - spread power across entire anode
  - cathode current density relatively low
  - mainly sterilization
  - radiation source & sterilization target areas the same
  - panels on both sides provides self - shielding



- **Pixilated DAXS**
  - cold cathode arrays
  - electronically address small groups to make Xel
  - microseconds
  - panels replace tube on gantry
  - fast imaging
  - stationary CT
    - others: GE, Siemens, Philips, Xintek
  - formidable current density requirements



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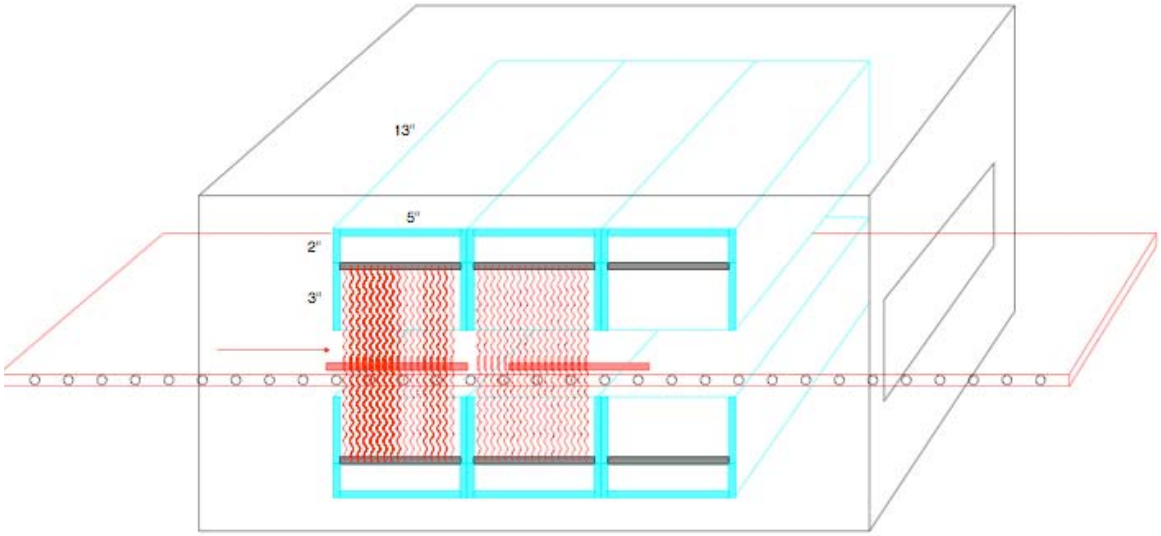
SCBI Basic Design



- Bench-top cabinet, FPXS panels (100kV) on either side, mostly self-shielding
- Double lining of 1/16” lead, interlocks
- Entirely self-contained - no external cooling; use 110 AC wall socket
- Blood bags pass between panels: conveyor or slide tray
- Redundancy - can operate with just one panel up and one down
- Designing panels for 8,000 hours lifetime - 250 bags/day for 10 years
- Small footprint: 26 x 24 x 34” in side loading model; weight ~ 100 kg
- Fast dose: four 400 ml bags < 2 min.
- Later add bar code scanners, automatic dosimetry, ISBT 128 output

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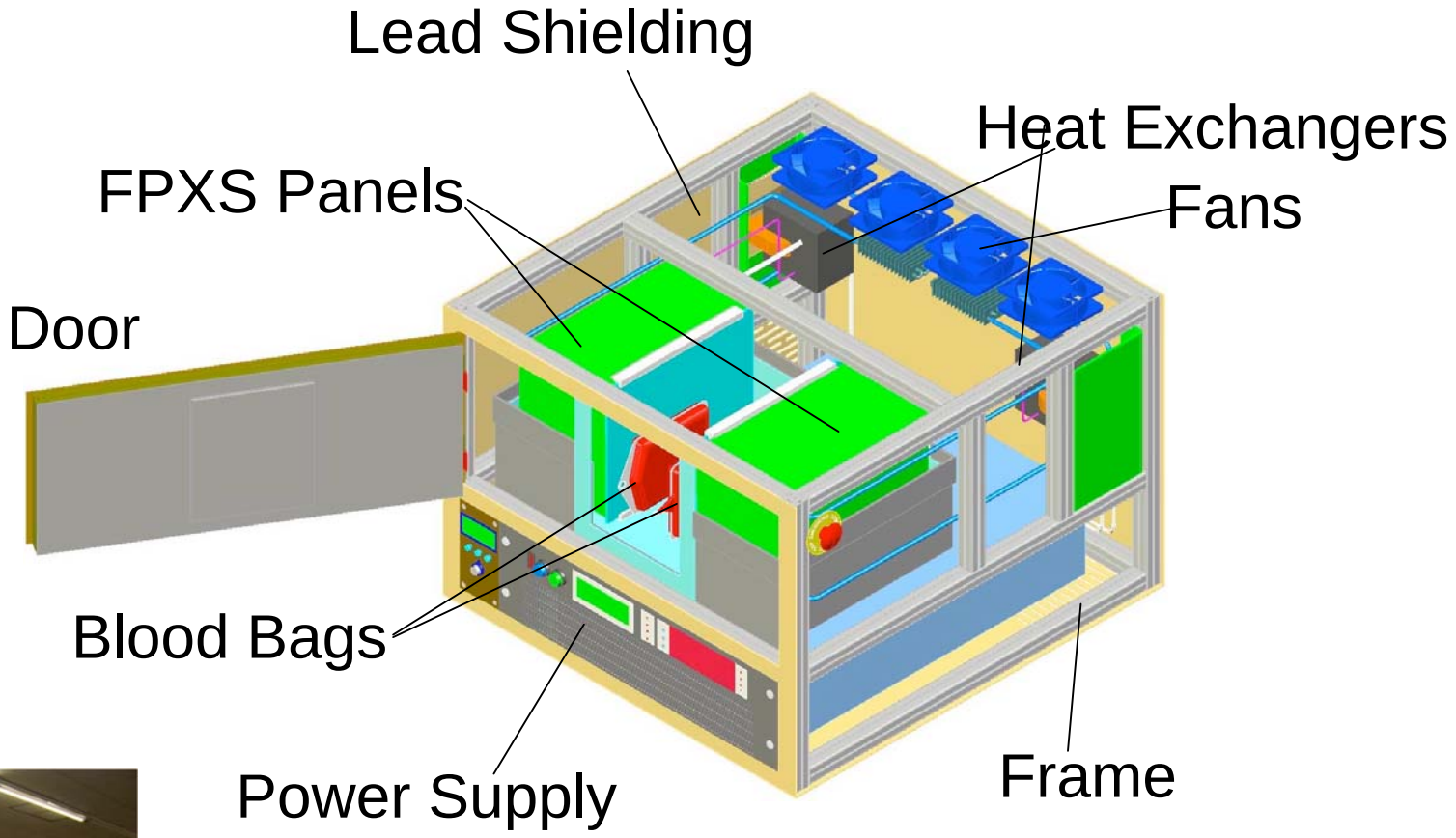
SCBI - 0



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SCBI - 1 Exterior

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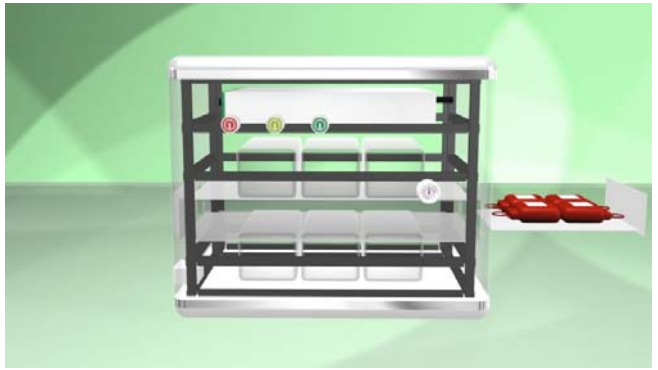
SCBI -1 Operation

- **Tray Out and Load**
  - interlocks prevent X-rays

- **Tray In**
  - radiation dose controlled by timer

- **Exit Tray Out**
  - radiation shut off before door opens

- **Variations**
  - add conveyor module
  - one-sided tray
  - front-loading tray



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SCBI Versions

- **FDA approval**
  - 1020.40, other FDA compliance
  - 510k - should to be as close to predicate device as possible
  - can't add all features at once
  - software validation

- **SCBI - 1**
  - rack mount power supply
  - manual operation, timer
  - slide tray
  - 4,000 hour panels
- **SCBI -2**
  - conveyor module add on
  - bar code scanners
  - PC or front console operation, ISBT-128 output
  - 8,000 hour panels
- **SCBI - 3**
  - optional internal dosimeters
  - data feed to Stellarray service
  - panels with on board amplifiers

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SCBI 1.0

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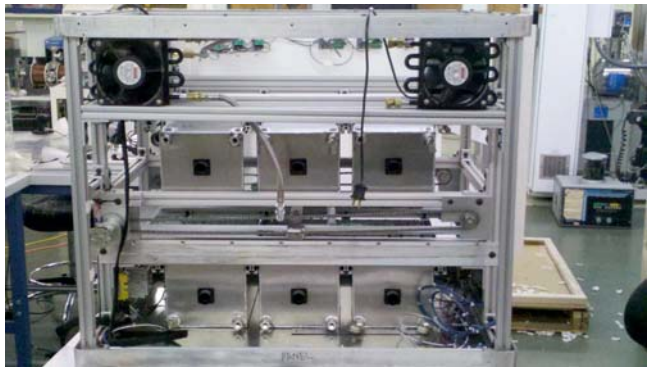

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Cold Cathode Arrays

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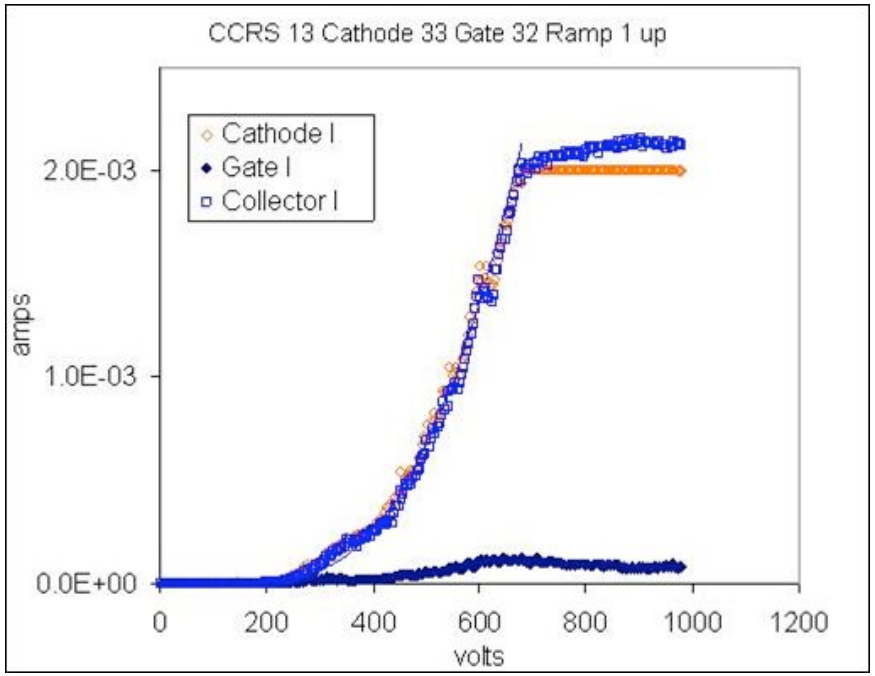
Phosphor Anode

I-V Data



CCRS 13 Single Array Test Summary:

- Each array produced large-area image on phosphor screen
- Collected current ~2mA ➔ 1.2 mA/cm^2 far exceeded goal of > 0.013 mA/cm^2
- >80 lines per array
- Other cold cathodes for 30 A/cm^2

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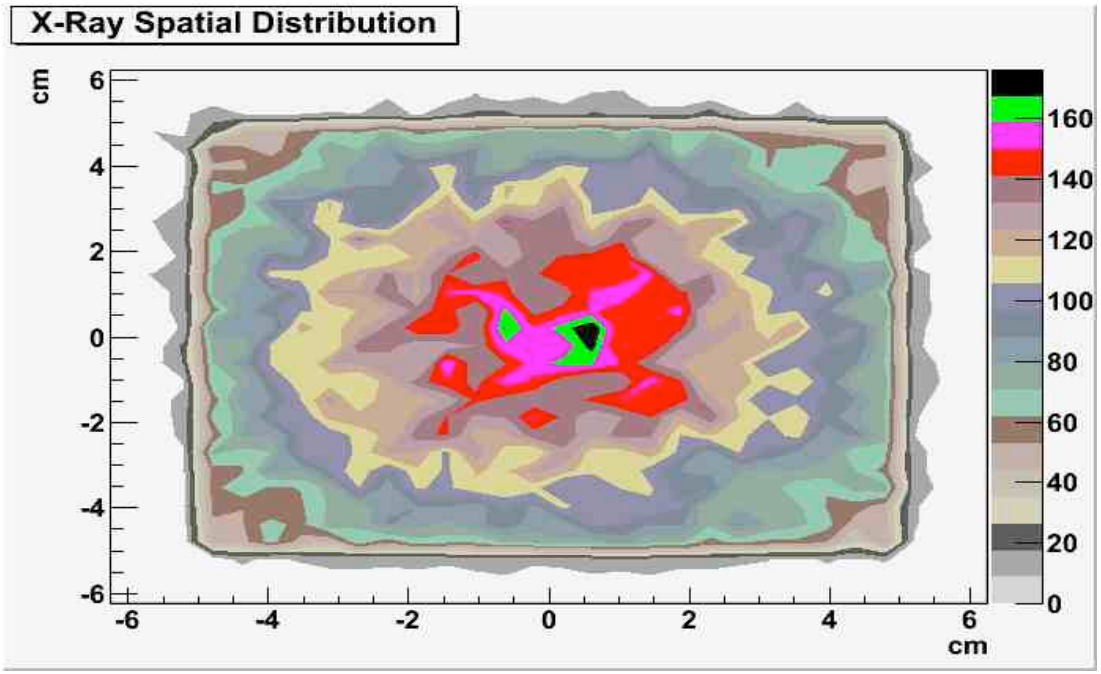
Areal Distribution



- X-ray flux concentrated at center of the panel
- Experimentally verified
- Redesigning cathode arrays to emit more current at sides

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System/Dose Modeling

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Input

Power		
Power	1.2	kW
Exposure Time	1	min
Price per kWh	$0.10	
Anode		
Width	10	cm
Length	10	cm
Thickness	6	mm
Distance to Window	3	cm
Window		
Window Material	Glass	
Thickness	2	mm
Irradiation Chamber		
Length	10	cm
Width	10	cm
Height	10	cm
Packaging		
Material	Polystyrene	
Thickness	0.5	mm
Target Substrate		
Material	Blood	
Thickness	1.5	cm
Length	10	cm
Width	10	cm
Desired Dose	0.025	kGy
Density	1.385	g/cc

Model 25 Gy

Output

	50KV	100KV	150KV	200KV	W-Cu 250KV
Physical Constraints					
Collimation Factor	1.00	1.00	1.00	1.00	1.00
Area of Target	100	100	100	100	100
Area of Anode	100	100	100	100	100
Power					
Operating Current	24.00	12.00	8.00	6.00	4.80
Quantum Efficiency	0.0082	0.0117	0.0153	0.0190	0.0226
Anode Current Density	2.40E-04	1.20E-04	8.00E-05	6.00E-05	4.80E-05
Total Energy Required	6	0	0	0	0
Total Energy in kWh	0.00	0.00	0.00	0.00	0.00
Photons/sec	1.23E+15	8.81E+14	7.65E+14	7.12E+14	6.77E+14
Dose Information					
Dose Rate	6.16	45.85	77.70	109.30	139.72
Total Dose	6.16	45.85	77.70	109.30	139.72
Required Exposure Time	4.06	0.55	0.32	0.23	0.18
Electricity Cost per kg	$0.00	$0.00	$0.00	$0.00	$0.00

- **Two 10 x 10 cm panels, either side of one bag**
  - 500 W each panel
  - bag the same area as panels
- **Note importance of matching areas**
  - too much source area and we waste flux

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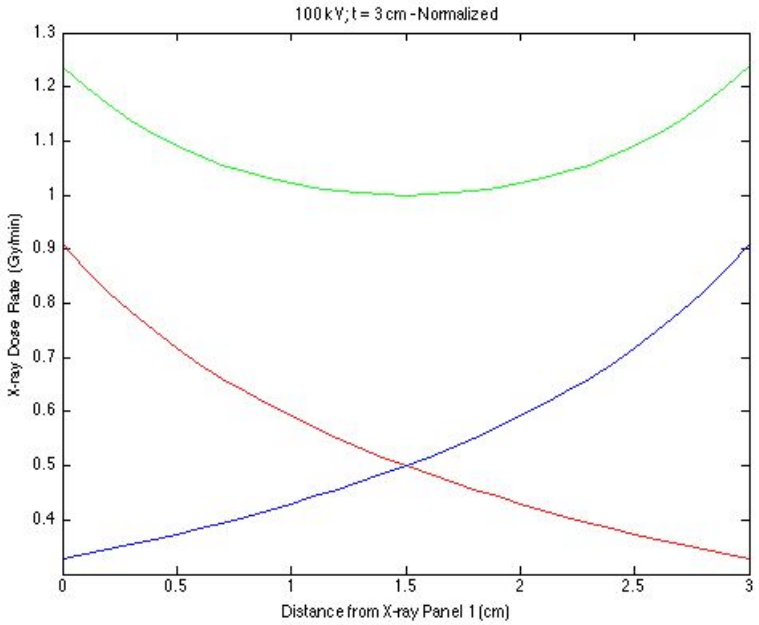
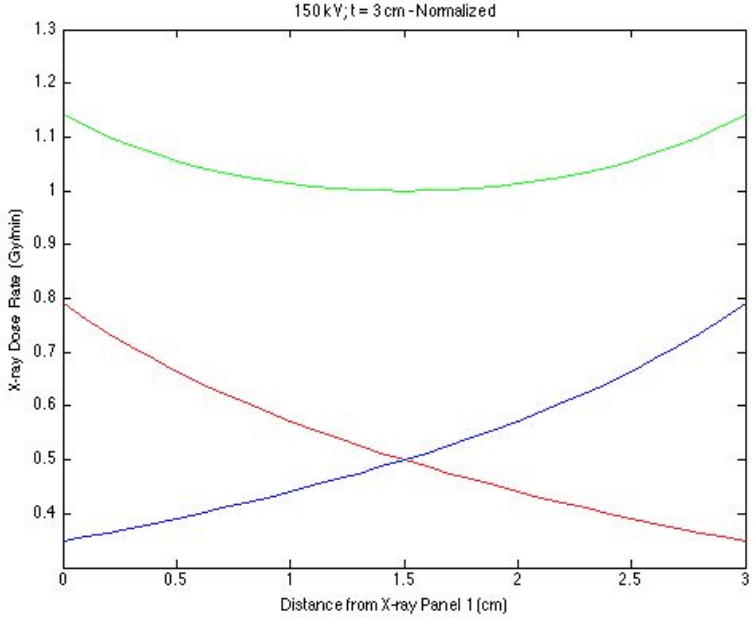
Depth-dose Calculations





100 kV, 1 bag
Max = 1.25 x 25 Gy = 31.25 Gy

150 kV, 1 bag
Max = 1.15 x 25 Gy =28.75 Gy

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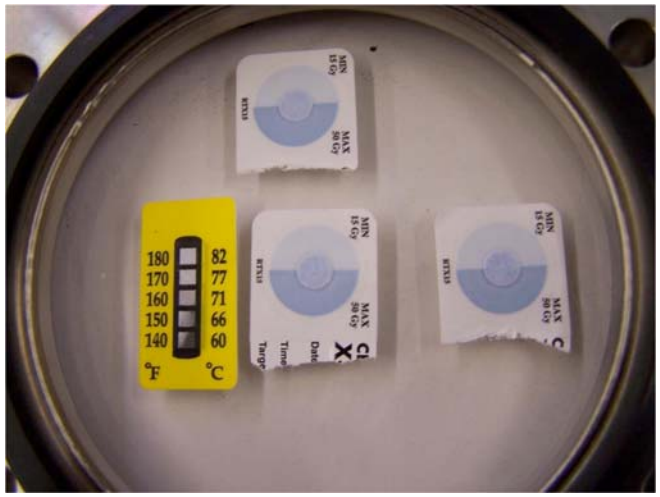
Calibration and Dosimetry

- **Practice now (gamma and X)**
  - periodic calibration
  - dose administered by controlling irradiation timer
  - verify irradiation, or (very roughly) dose, with indicator tags
- **Calibration of SCBI (development, production)**
  - alanine tabs
  - film
- **Calibration of SCBI (periodic in field)**
  - technician verify with phantom
  - film?
- **In-line**
  - also rely on time and tags
  - would like more precise tags
  - internal dosimetry
    - electronic?
    - ion chamber



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Platform Technology

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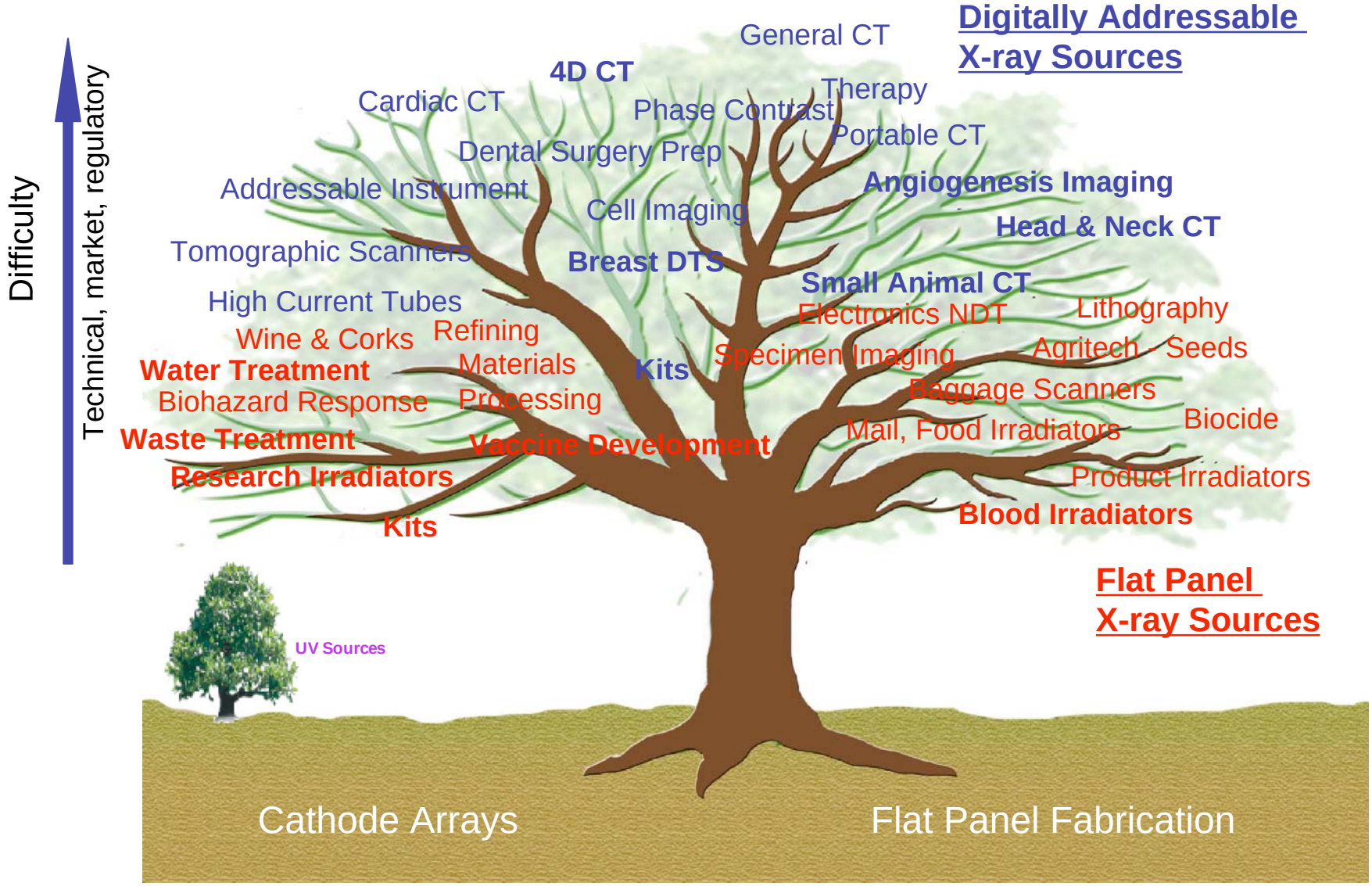

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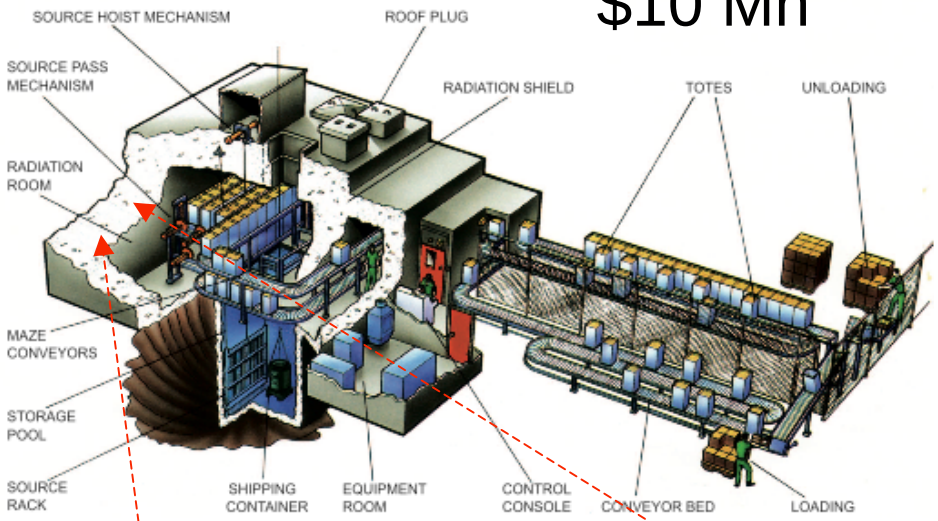
Panoramic Irradiators

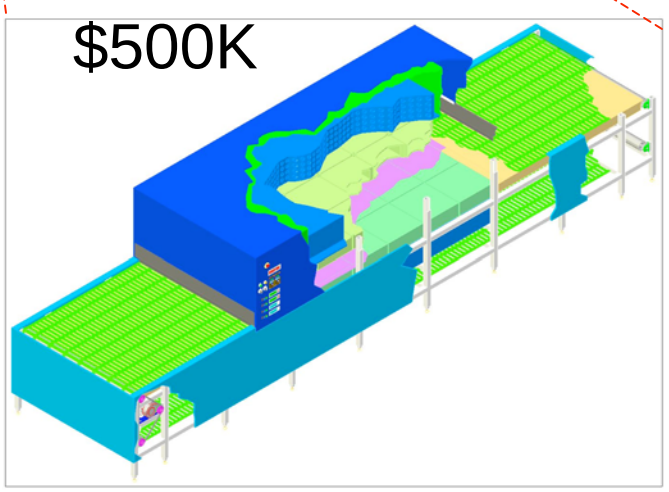
- Medical Products, ex factory
  - U.S. market (radiation):
    - ~ $469 Mn in 2008, $609 Mn 2013 (GIA)
  - Sutures, staples, syringes, IV, implants
    - 1 - 25 kGy, penetrate packaging
    - kills bacterial, prion, virus, protozoal
- City block, $10Mn, centralized
  - Isotopes & e-beam

$10 Mn



- Stellarray FPXS systems
  - FPXS panels above & below
    - same dose, quicker, self-shielding, lower energy
    - 5% capital costs, lower operating costs
    - decentralized = MUCH lower inventory costs
- Market - demonstrate, sell systems & panels
  - Bench/tabletop systems - direct sales
  - Shipping bay/conveyor - with integrators

$500K



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