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Midwest Medical Device Sterilization Workshop: Opportunity Case Study 2: X-Ray as an opportunity for contract sterilization facilities.

Agenda

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- Introduction to the case to be studied
- General overview over technologies
- Option 1: TT1000 X-Ray Facility
- Option 2: NORDION Gamma Facility
- Technical Comparison Gamma / X-Ray
- Financial comparison: Initial investment
- Financial comparison: Operating cost
- Conclusions

Introduction to the Case

- A company plans to build a contract irradiation facility to offer irradiation services to medical device customers.
- The company already owns the land this facility is to be built on.
- Warehousing and material handling requirements should be small. (Lean manufacturing “just in time” approach)
- The company has identified an initial monthly market demand of 1`700 pallets of low density VDMAX 25 product to be sterilized and wants to be able to treat this product on a pallet vs. breaking it down into boxes.
- Dose uniformity for low density product should be 1.6 or better.
- Regional electricity costs are assumed to be 10. cents / kWh.

Introduction to the Case

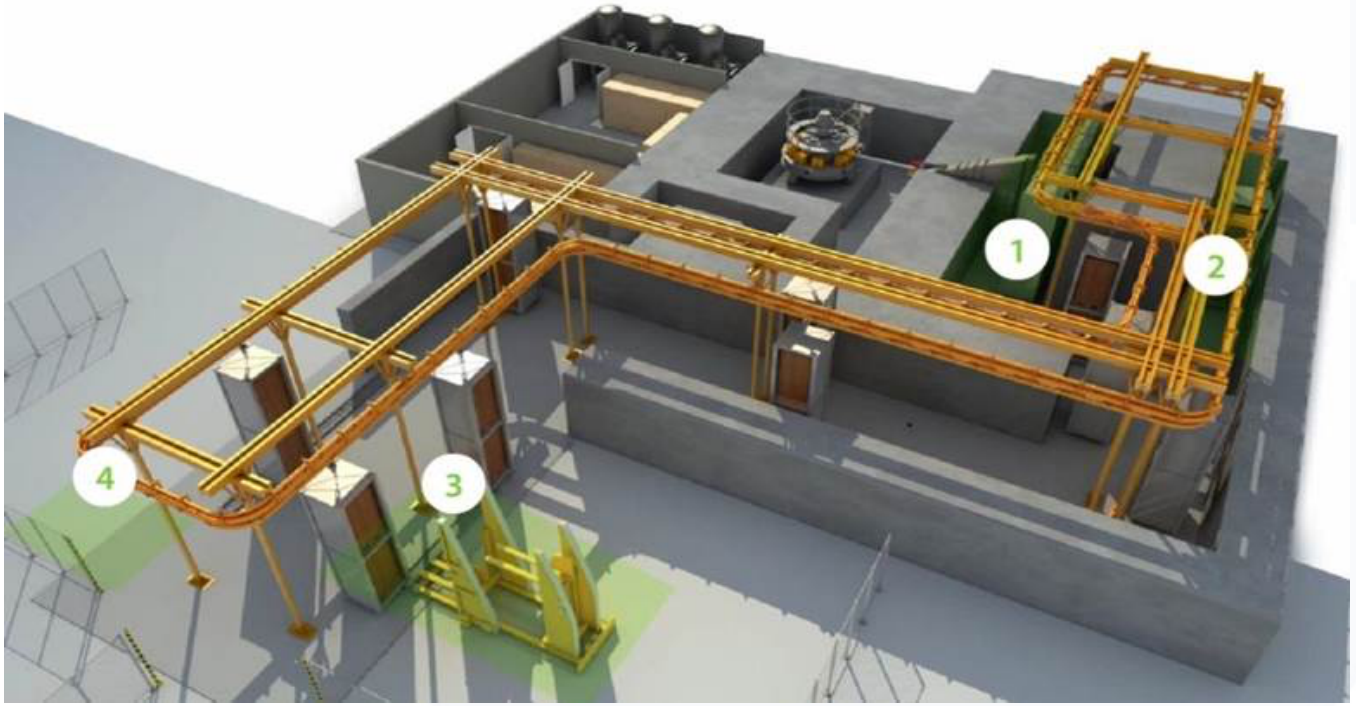
- The case study develops technical and financial considerations from the view point of a contract sterilization facility when choosing X-Ray vs. Gamma. Ruling out e-beam for reasons of penetration and dose uniformity.
- Dose uniformity, processing flexibility, initial investments, running costs, market risks will be estimated and discussed.
- The company plans to grow to a total capacity of 5,100 pallets a month within 10 years of low density VDMAX 25 product as a reference.

General overview over technology, capability and limitations.

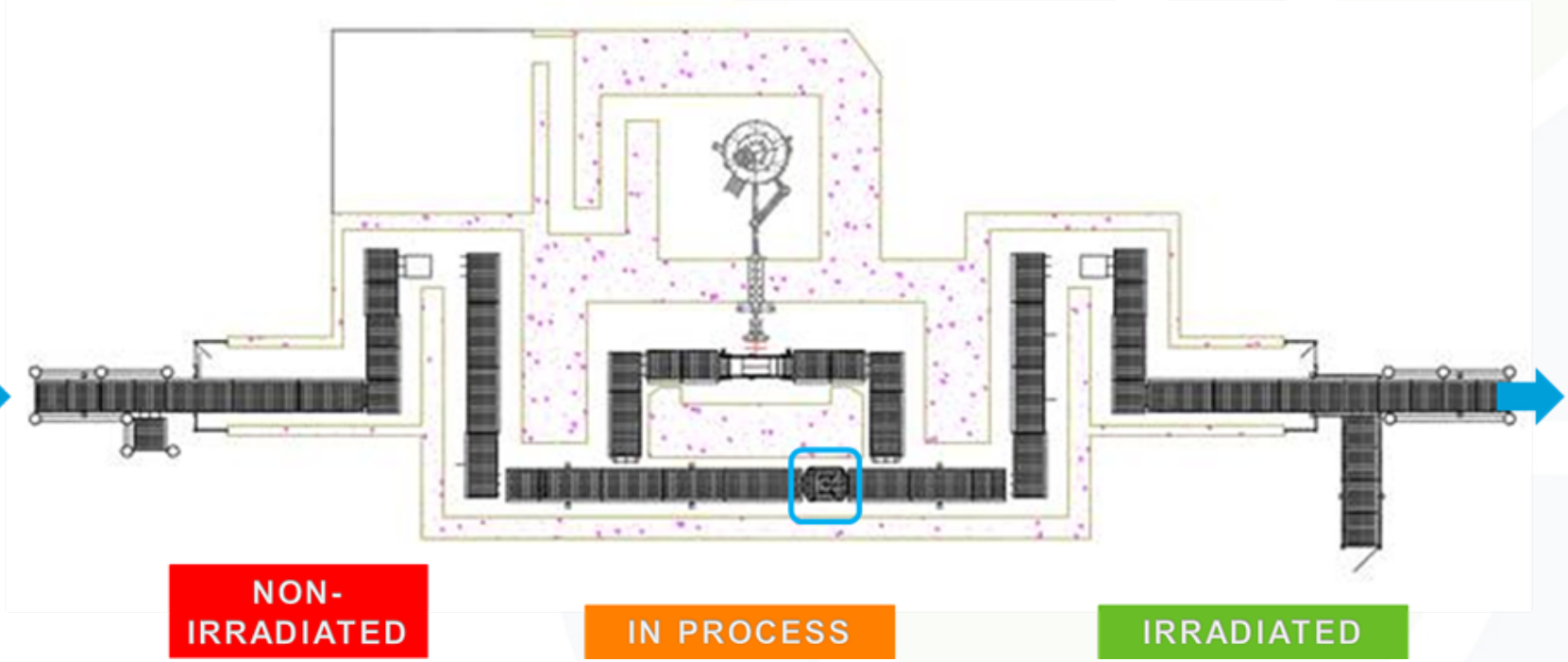
	Gamma	X-Ray	Electron beam
Presentation	Pallets / Totes	Pallets / Totes	boxes
Dose uniformity	Excellent	Very good	Limited
Electricity cost	Negligible	High	Small
Processing felxibility	Limited	Very Good	Very Good
Material Handling	Medium	Very Low	High
Market Risks	Medium	None	None
Maturity	Mature	Maturing	Mature
Process interruptions	Robust	Robust	Sensitive
Cooling requirements	Low	High	None
Throughput	Scalable (Costly)	Adjustable / scalable	Material handling
Shielding	High	High	High
Investment	Very High	High	High

Option 1: X-Ray Facility

- IBA TT1000 Design
- Pallet irradiator
- Dual pass rotation / translation
- Beam capacity 760kW

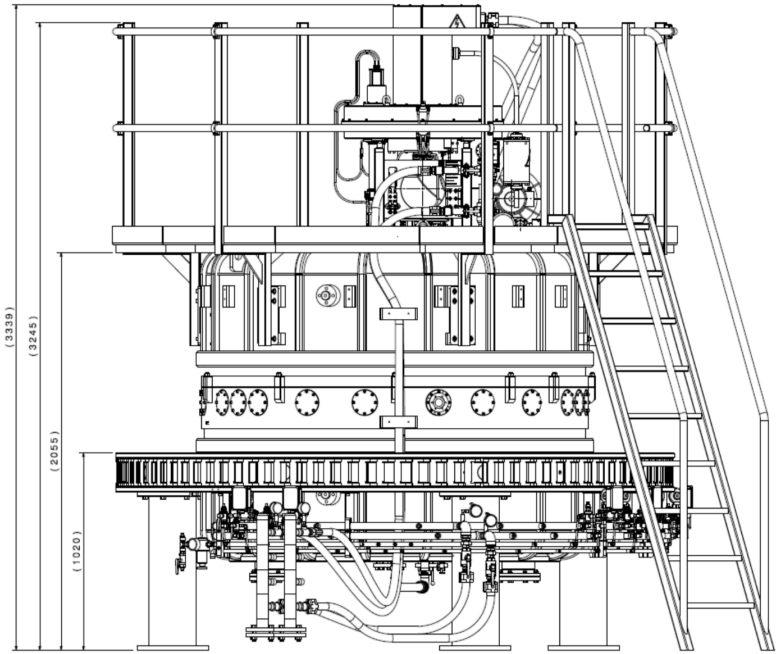


General overview over technology, capability and limitations.



General overview over technology, capability and limitations.

TT1000 – Accelerator footprint



View and dimensions of the TT1000 cavity with one final power amplifier (FPA), ladder and catwalk. The cooling manifold is also represented.

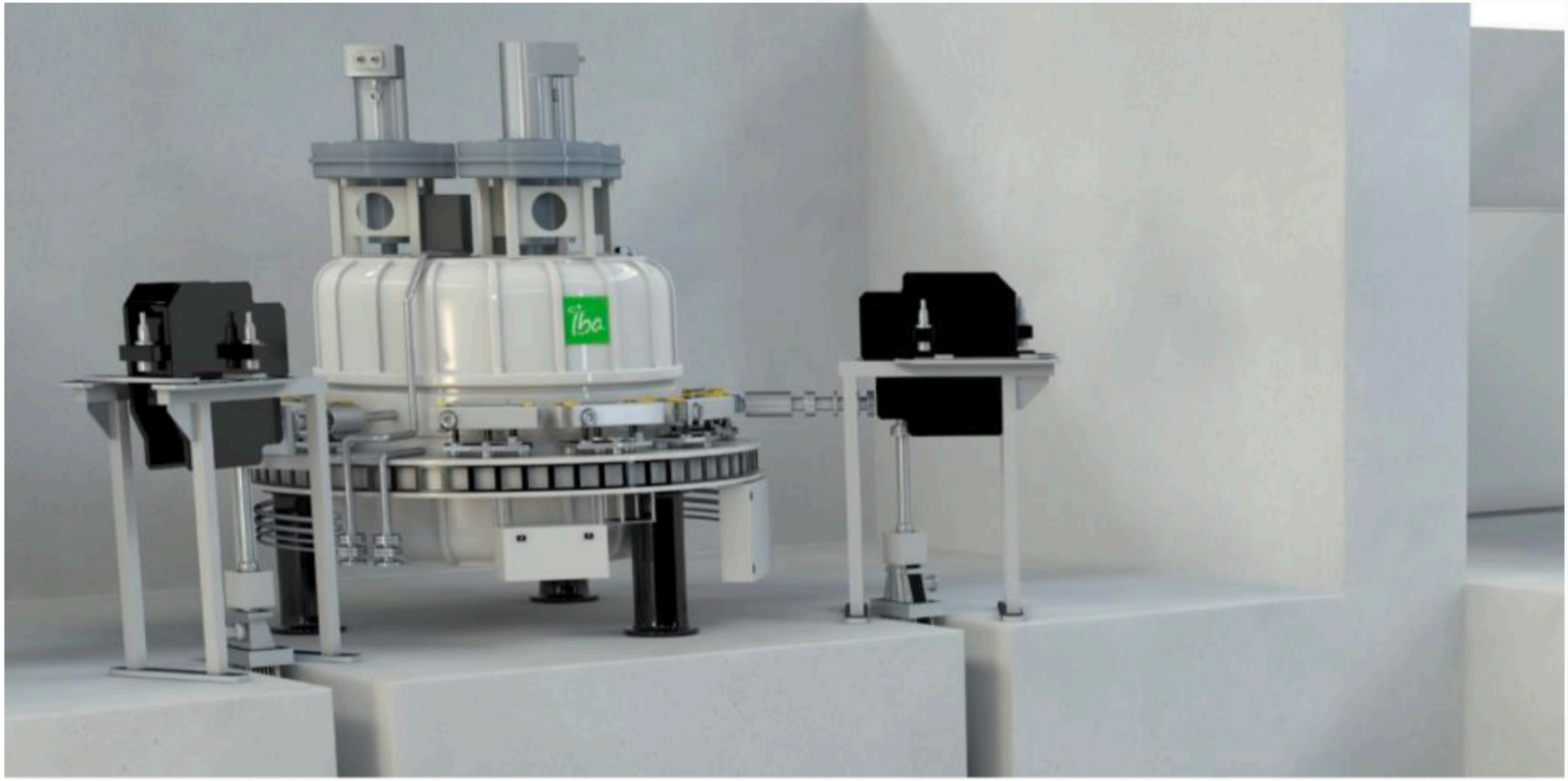
Rhodotron TT1000 dimensions:

- 4000 x 4280 x 3340 [mm]

Rhodotron Vault - Room Size

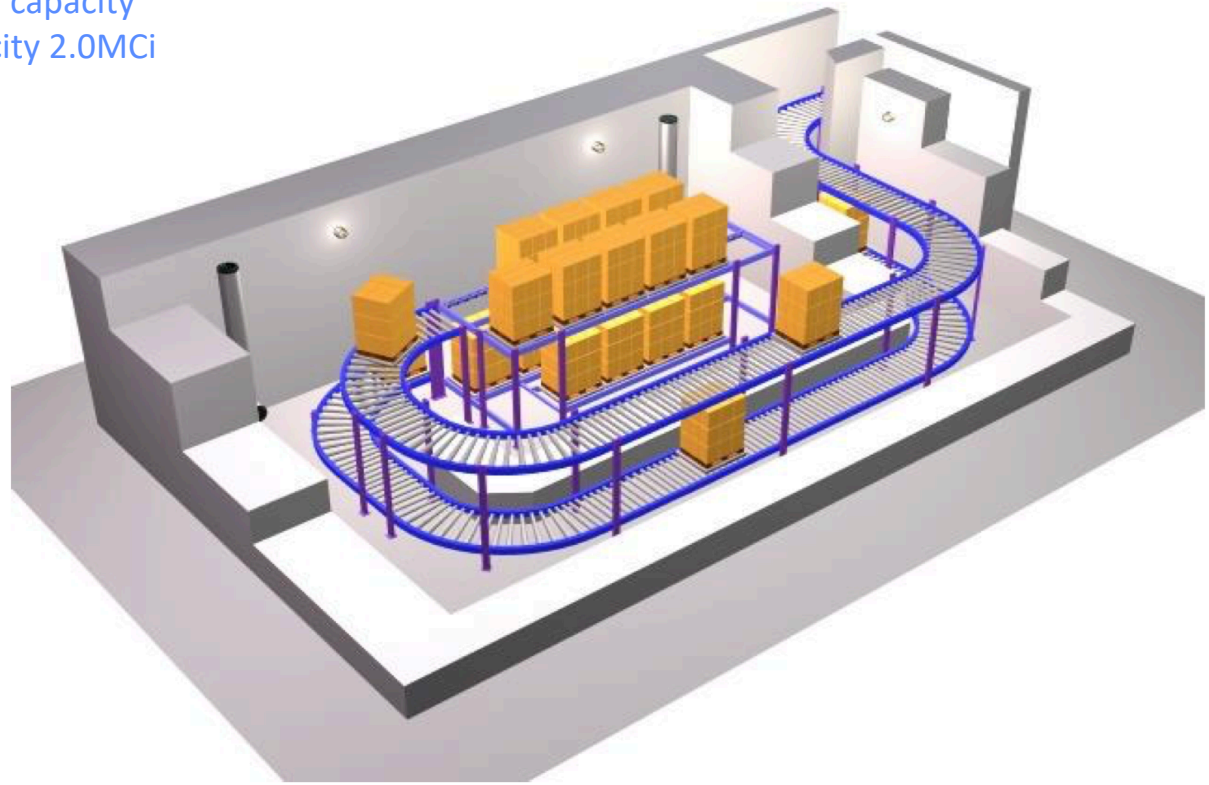
- Minimum 7.0m x 5.0m x 4.8m (WxDxH), depending on movable crane size
- Height under the hook: 4.4m
- The vault door or access will be at least 1.2m x 2.0m (WxH).

General overview over technology, capability and limitations.



Option 2: Gamma facility

- MDS NORDION Design
- 2-Pass Parallel Row Pallet irradiator
- 6MCi Shield capacity
- Initial capacity 2.0MCi



Technical requirements Gamma vs X-Ray

Attribute	Gamma	X-Ray
Pallet dimensions	40"x48"x 2.30m	40"x48"x 1.50m
Density	0.1g/cc	0.1g/cc
DUR	1.4	1.6
DMIN	26kGy	26kGy
DMAX	36kGy	42kGy
Throughput VDMAX 25	3.2 m^3 / h / MCi	3.4 m^3 / h / 100kW
Throughput VDMAX 15	5.4 m^3 / h / MCi	5.7 m^3 / h / 100kW
Available capacity year 1 VDMAX25	2MCi: 6.4 m^3 /h	560 kW: 19.1 m^3 / h
Required capacity year 10 VDMAX25	6MCi: 19.2 m^3 /h	560 kW 19.1 m^3 / h
Cooling requirement	15kW always	1.1 MW at capacity

Financial comparison: Capital

Gamma / CO60

Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	Total
Plant	2,000,000										
Shield	800,000										
Machine	6,000,000										
Cooling requirements	50,000										
Additiobal Isotope	$ 7,600,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 40,270,000
Depreciation		$ (934,800)	$ (1,266,310)	$ (1,557,044)	$ (1,812,017)	$ (2,035,629)	$ (2,231,737)	$ (2,403,723)	$ (2,554,555)	$ (2,686,835)	$ (17,482,649)
Investment in activity	$ 7,600,000	$ 10,295,200	$ 12,658,890	$ 14,731,847	$ 16,549,830	$ 18,144,201	$ 19,542,464	$ 20,768,741	$ 21,844,186	$ 22,787,351	$ 164,922,709
Total investment	$ 16,450,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 3,630,000	$ 49,120,000

Gamma: Initial investment 16.4 MD

Total investment 10 years: 49.1 MD

X-Ray (TT1000)

Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	Total
Plant	2,000,000										
Shield	960,000										
Machine + Conveyor	10,000,000										
Primary cooling	500,000										
Additional investments	$ -		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Total investment	$ 13,460,000	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 13,460,000

X-Ray: Initial investment 13.5 MD

Total investment 10 years: 13.5 MD

Financial comparison: Operation

Gamma / CO60

Operating Cost	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Anual Cost	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)
Isotope maintenance		$ (934,800)	$ (1,266,310)	$ (1,557,044)	$ (1,812,017)	$ (2,035,629)	$ (2,231,737)	$ (2,403,723)	$ (2,554,555)	$ (2,686,835)
Electricity cost	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)
Total operating cost	$ (2,050,000)	$ (2,984,800)	$ (3,316,310)	$ (3,607,044)	$ (3,862,017)	$ (4,085,629)	$ (4,281,737)	$ (4,453,723)	$ (4,604,555)	$ (4,736,835)

Gamma: Annual operating cost year 2: 2.9 MD

Gamma: Annual operating cost year 10: 4.7 MD

X-Ray (TT1000)

Operating Cost	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Anual Cost	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)	$ (2,000,000)
Consumed kwH beam	1,440,000	1,760,000	2,080,000	2,400,000	2,720,000	3,040,000	3,360,000	3,680,000	4,000,000	4,320,000
Consumed kWH (cooling)	2,200,000	2,688,889	3,177,778	3,666,667	4,155,556	4,644,444	5,133,333	5,622,222	6,111,111	6,600,000
Total electricity cost	$ (364,000)	$ (444,889)	$ (525,778)	$ (606,667)	$ (687,556)	$ (768,444)	$ (849,333)	$ (930,222)	$ (1,011,111)	$ (1,092,000
Electricity cost Plant	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (50,000
Total operating cost	$ (2,414,000)	$ (2,494,889)	$ (2,575,778)	$ (2,656,667)	$ (2,737,556)	$ (2,818,444)	$ (2,899,333)	$ (2,980,222)	$ (3,061,111)	$ (3,142,000

X-ray: Annual operating cost year 1: 2.5 MD

X-ray: Annual operating cost year 10: 3.1 MD

Conclusion

- X-Ray today offers a lower initial capital investment vs. Gamma
- For X-Ray: Full capacity can be available at start up providing a competitive advantage due to lower turn around times
- Initial operating cost of a X-Ray facility are somewhat lower, and capacity increases make operation relatively even more attractive.
- X-Ray requires no recurring investments vs. Isotope decay
- Operating costs improve greatly as capacity increases for X-Ray
- No market supply risks vs. Co60
- X-Ray Technology maturing and bigger players entering X-Ray as repeat customers.