Meeting Summary
Meeting to Discuss the Sealed Source and Device Registration Requirements
And the Application process
Held Between the NRC and Widetronix
September 1, 2011
Rockville, MD

This document summarizes the discussions and conclusions of a meeting held between the Nuclear Regulatory Commission (NRC) and Widetronix staff regarding the licensing and device registration process for a beta-voltaic device containing tritium for electric power generation.

Attendees:

NRC
Duncan White, Chief, ASPB/MSSA/FSME
Kevin O'Sullivan, Chief, RB-B/DIL/FSME
Daniel Collins, Deputy Director, Region I/DNMS (on conference call bridge line)
John Jankovich/FSME
Stephen Poy/FSME
John O'Donnell/FSME
Tracey Stokes/OGC
Monica Orendi/Region I (on conference call bridge line)
Donna Joustra/Region I (on conference call bridge line)

New York State Health Department (on conference call bridge line)
Robert Dansereau/Deputy Director
Desmond Gordon

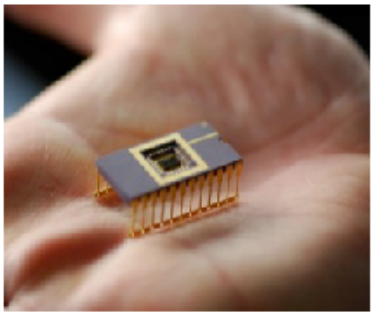
Widetronix
Jonathan Greene/CEO
Christopher Thomas
Samuel Portnoff

Summary:

On September 1, 2011, the NRC staff and representatives of Widetronix, located in Ithaca, NY, held a meeting to discuss the licensing and device registration requirements for a new concept of using tritium in a beta-voltaic device to generate electric current. The specific objective of the meeting was to discuss the regulatory framework for such an application of radioactive material because the use of radioactive material for electric current generation is outside the scope of the regulations currently in effect, i.e., 10 CFR 31.5.

The representatives of Widetronix presented an overview of the design and questions about the regulatory requirements (see presentation slides below). After the presentation the NRC staff,

with support from the New York State Health Department staff, discussed the issues regarding the application process for such a new product. The NRC staff also outlined how members of the public could request changes to the regulations, how a license applicant such as Widetronix could request an exemption from the regulations, and the compatibility of the Agreement State regulations with those of the NRC.



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BETAVOLTAIC BATTERIES

AUTONOMOUS POWER FOR WIRELESS SENSORS

Spring/Summer 2011

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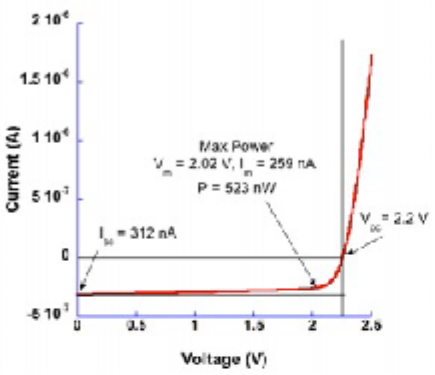
AGENDA

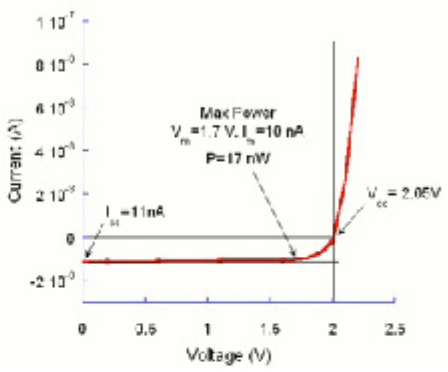
- Overview of betavoltaic technology
- Widetronix optimizations
- Market focus and product roll-out
- Discussion of regulatory strategy
- Next steps

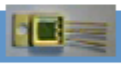
SINGLE CHIP IV CURVE: Pm^{147} & H^3



Pm^{147}	
V_{oc}	2.2 V
I_{sc}	312 nA
Max Power	523 nW
Fill Factor	0.74

Power Output: 2μW/cm²



H^3	
V_{oc}	2 V
I_{sc}	11 nA
Max Power	17 nW
Fill Factor	0.75

Power Output: 68nW/cm²

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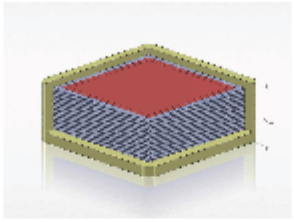
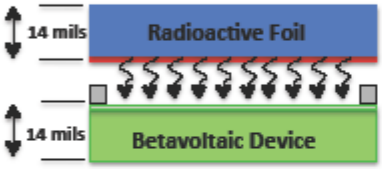
DEVICE EVOLUTION





Planar design

- Separate diode & foil
- Inefficient volumetrically
- Lowest power density

Wafer thinning

- Separate diode & foil
- Improved volume utilization
- Better power density
- Stacking achievable

Isotope on chip

- Integrated diode & isotope
- Highest volume utilization
- Highest power density
- Stacking achievable

Power output of planar betavoltaic limits market applications

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PROTOTYPE MILESTONES

BV Type (N = NICKEL) (T =TRITIUM)	Active Area	Est. Output (nA/cm^2)	Device Output (nA)	Production Status
Planar Device	5mm x 5mm	40	10	Current
EF10-N	5mm x 5mm	60	15	Current
EF10-T-3-2	5mm x 5mm	188	37	Q4 2011
EF20-T-2-2	5mm x 5mm	380	95	Q2 2012
EF50-T-2-2	5mm x 5mm	717	239	Q4 2012
EF50-T-1-1	5mm x 5mm	1,916	479	2013
EF50-T-1-1	3mm x 3mm	1,911	172	2013
EF50-T-1-1[+]	3mm x 3mm	2,944	265	2014

[+] **Efficiency improvement brought on by direct deposition of radiation source onto SiC device**

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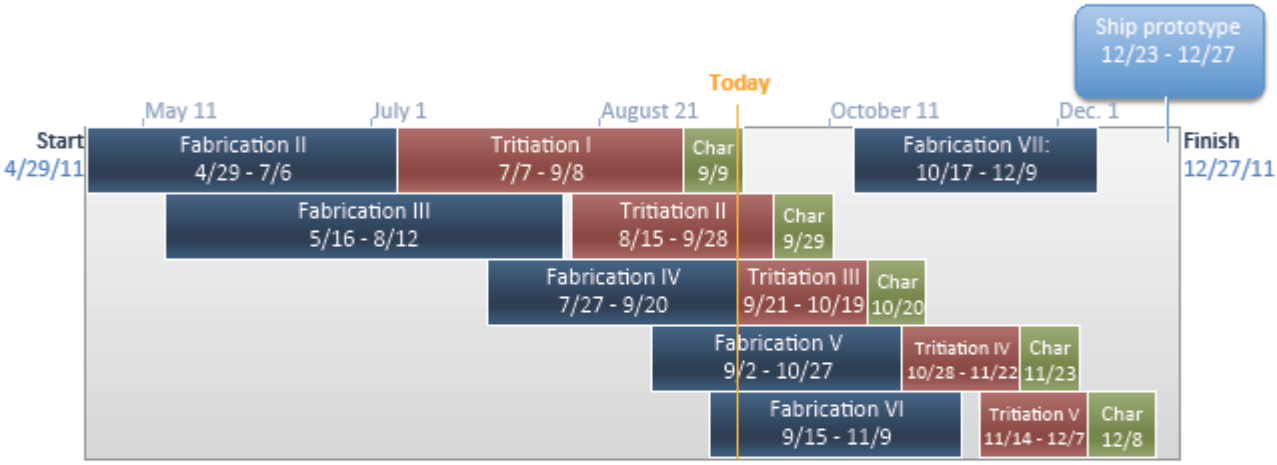
SCHEDULE SUMMARY



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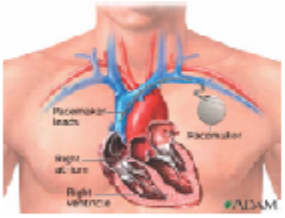
DRIVERS ARE SMALL SIZE, FLEXIBLE LIFETIME

Current batteries:

- **Bulky -** does not meet requirements for MEMS sensors
- **Discharge/replacement** – adds >80% to cost of ownership*
- **Limited lifetime** – harsh environments reduce lifetime



Widetronix solid state battery:

- **Small size** (mm) **& flexible lifetime** (days to decades)
- **Continuous current/voltage** trickle charges & powers directly
- **Compliments** thin film battery & energy harvesting technologies
- **Safe to use** with standard semiconductor packaging

*Darnell Group 2007

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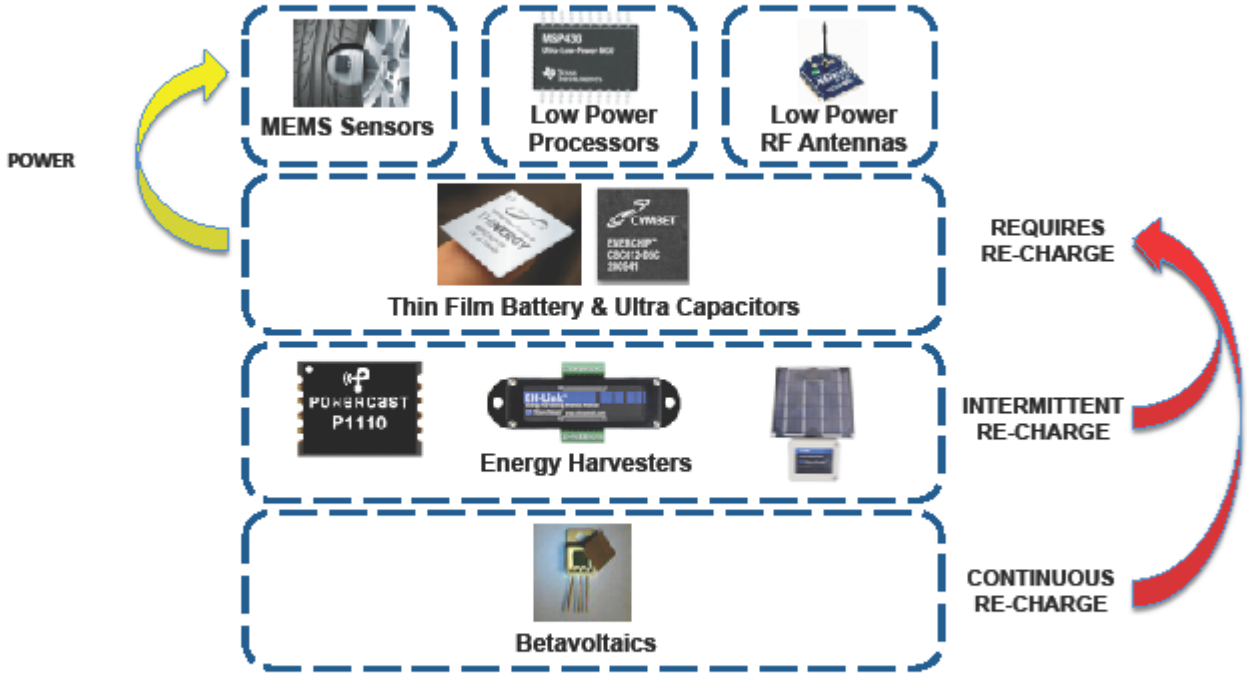
AUTONOMOUS SENSORS



Enabling technology for ultra low power sensors

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PRODUCT ROLL-OUT

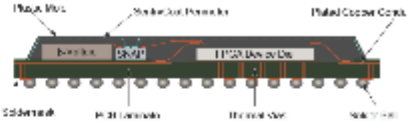
POWER	APPLICATION	TIMELINE		
		PROTOTYPE	EVALUATION	MARKET
1 µW	• Anti-tamper circuit • MEMS implant	12/11	2/12	5/12
10 µW	**• MEMS implant** **• Anti-tamper circuit** **• Wireless sensors**	**2/12**	**6/12**	**3/13**
100 µW	• Cardiac/Neural Implants • Autonomous sensors	6/12	11/12	12/13

Initial sales as component supplier to prime contractors

MARKET ENTRY

ANTI-TAMPER CIRCUIT - 1 µW

- **APPLICATION** FPGAs & micro-controllers
- **DRIVER** Lifetime (25 yrs)
- **UNITS** 10,000 (2012) to 150,000 (2015)
- **PRICE** $500/battery
- **MARKET** $100M

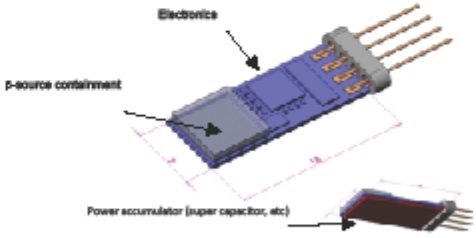


ITT

LOCKHEED MARTIN

BIOMEDICAL IMPLANTS - 1 µW

- **APPLICATION** Physiological monitoring
- **DRIVER** small size & lifetime (15 years)
- **UNITS** 200,000 (2015) to 1M (2018)
- **PRICE** $500/battery
- **MARKET** $500M



$12B Implant Co.

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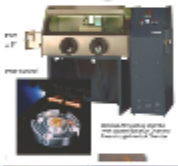
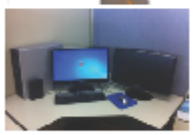
COMPLETE PACKAGING CAPABILITY

Two 450PM Probe Stations, vibration tables, Faraday cages

TPT semi-automatic wire and die bonder



Venus IV Seam Sealer



SILVACO device modeling workstation

2 Fabrication engineers
1 Product roll-out engineer
1 Applications engineer

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REGULATORY GOALS

LONG TERM

- Sell betavoltaic batteries to commercial partners
- Sell devices with integrated betavoltaics to commercial partners
- Sales for industrial, medical, and military applications

SHORT TERM

- Sell betavoltaic batteries and devices to partners for R&D
- Reduce regulatory burden on commercial partners.
- Identify correct long-term pathway for general sales

CURRENT REGULATIONS

- GL device reqs outlined in 10 CFR 31.5(a)

  "… byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or producing light or an ionized atmosphere."

- Florida approved City Labs' device under reg
- NRC disagreed with that decision
- Result – Florida – GL, NRC – SL, Elsewhere - ?

REGULATORY UNDERSTANDING

- To sell betavoltaic to unlicensed company the product must have GL
- To receive a GL for a product:
  - Sealed source or device registered and
  - Listed in 10 CFR 31.5(a)
- Betavoltaics don't appear in 10 CFR 31(a), therefore they cannot be generally licensed

GL QUESTIONS

- What can be done to allow betavoltaics to be GL?
- Does a general license for a product broadly apply to the NRC and all agreement states?
- Can an R&D betavoltaic receive exempt status?

SSD REGISTRATION

- Can SSD for one package allow for variations in type and quantity of RAM?
- Can packages of similar design, but different size, be registered under the same SSD?
- Can betavoltaic chips be registered as sealed source?
- How does SSD with SL chip affect customers using them.

COMMERCIAL DISTRIBUTION

- What licensing do we need to distribute betavoltaics to:
  - Companies & consumers not licensed to work with radioactive material
  - Military customers
  - Hospitals
- Does the military fall under the jurisdiction of the NRC or is there another regulatory agency for them?
- Do medical devices enabled by betavoltaics (regulated by the FDA, but with NRC SSD registration) need to be generally licensed for doctors to work with them?

THANK YOU

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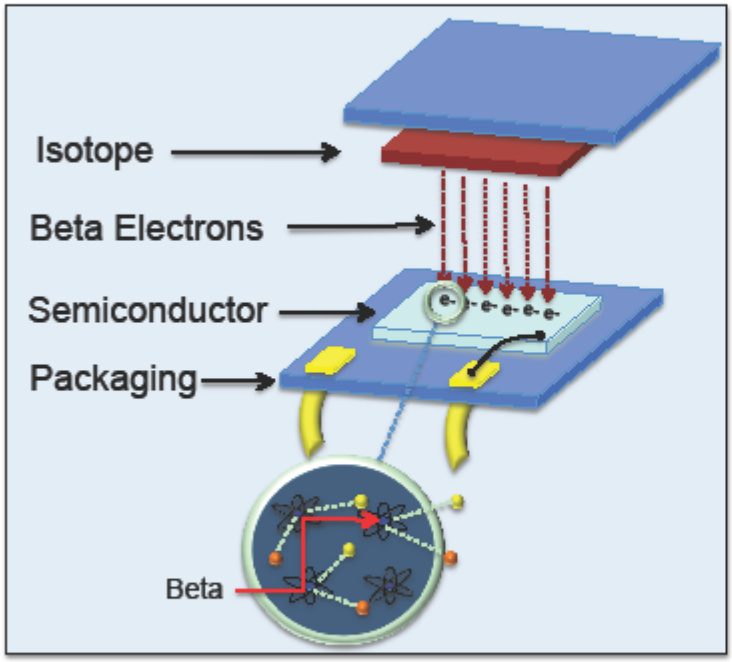
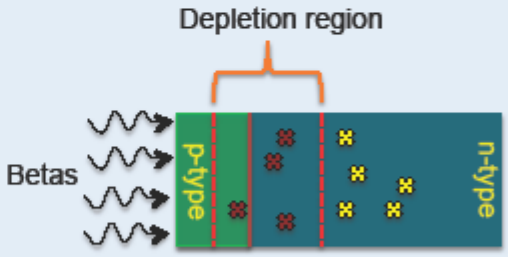
TECHNOLOGY OVERVIEW



- SiC is most efficient semiconductor
- Isotope customizes lifetime > 25 yrs
- Power density > chemical batteries
- Robust in wide temperature range
- H^3 betas stopped by dead skin



1 PATENT GRANTED & 8 PATENTS PENDING

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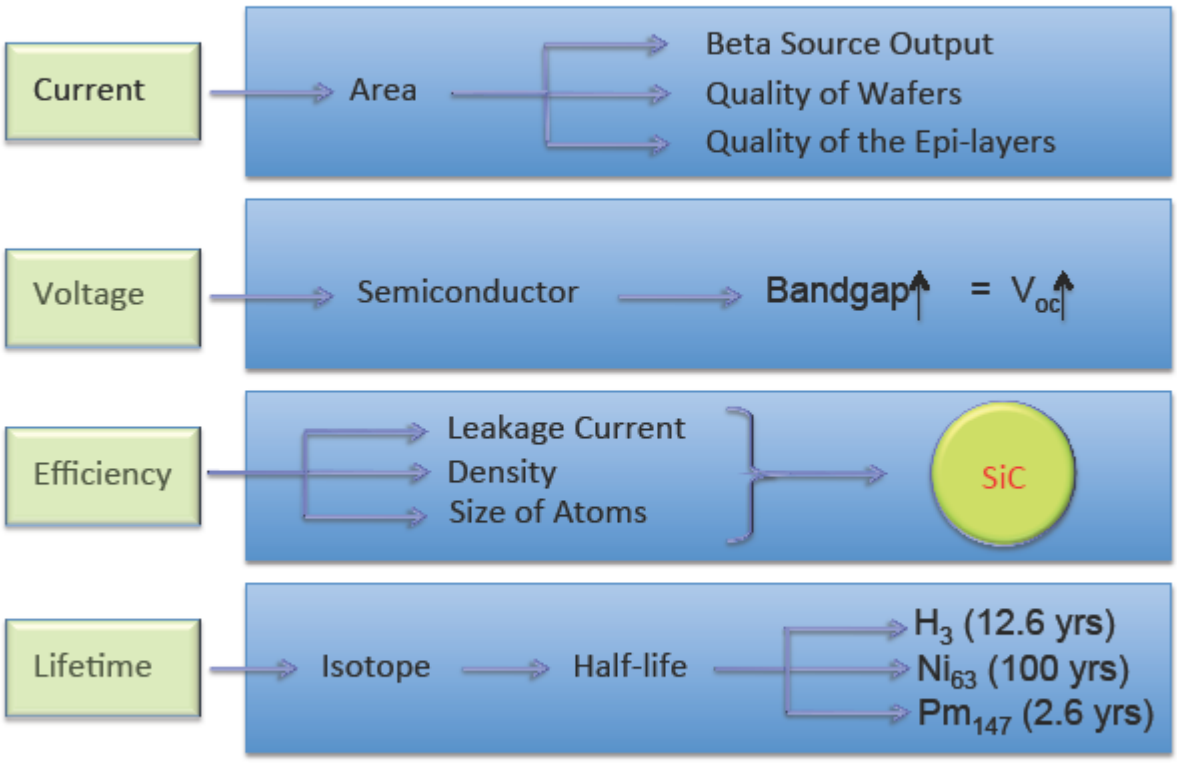
KEY PARAMETERS



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