Introduction and Logisitcs

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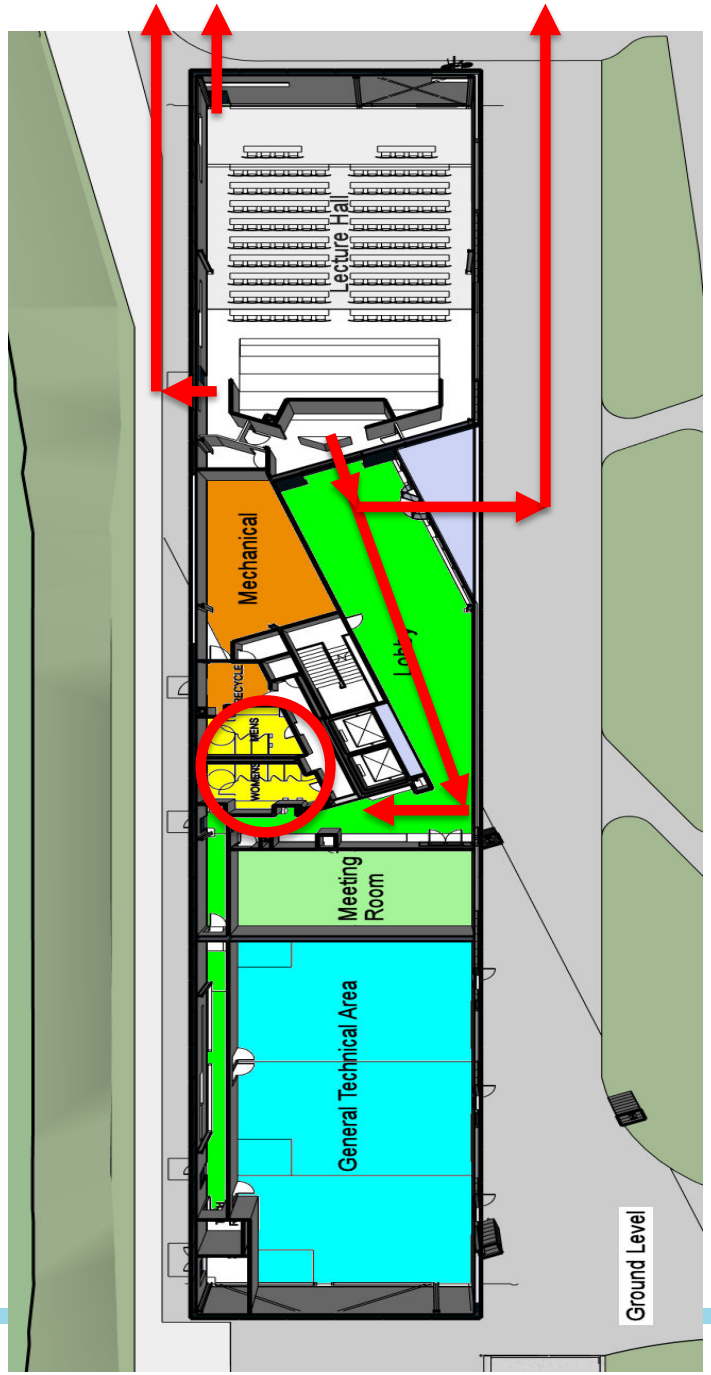
Midwest Medical Device Sterilization Workshop

18 September 2019

Fire/Tornado Safety

- Tornado – Bathrooms



Fire – Parking Lot

Fermilab

Fermi National Accelerator Laboratory

- National Laboratory: Funded by the Department of Energy (OHEP)
- Mission: High Energy Physics Research (Discovery Science)
- To carry out that mission Fermilab designs, builds, & operates: High Energy, High Power (MW) Accelerators that must have very high reliability
- 6800 acre site, ~$360M/yr budget, Staff of 1700, > 2200 users
- 350 Accelerator scientists and engineers + 300 technical staff (+ANL)
- Largest collection of accelerator experts in the world
- Broad skills in accelerator design, simulation, fabrication, integration & test
- Also well versed in industry, university, and international partnerships

Illinois Accelerator Research Center (IARC)

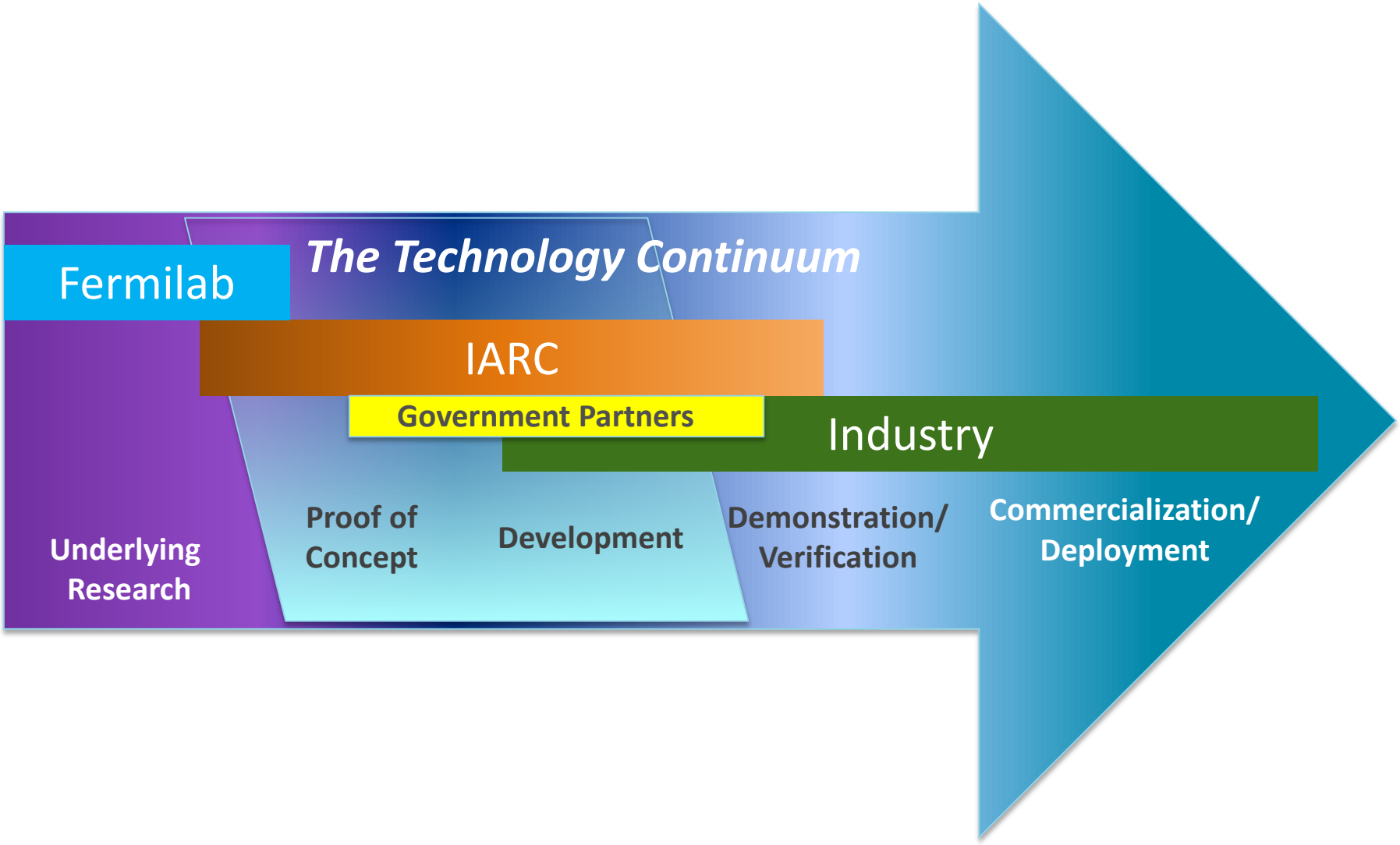
- The opportunity for Fermilab: We build accelerators for a living….
- IARC = opportunity to use our staff and capabilities to have a large impact on future industrial accelerators and applications

IARC is a joint DOE and State of Illinois DCEO funded project
$ 70 M complex on the Fermilab site

Mission

Partner with industry to exploit technology developed in the pursuit of science to create the next generation of industrial accelerators, products, and new applications.

What is IARC's role in the development process ?



What can IARC do for Industry?

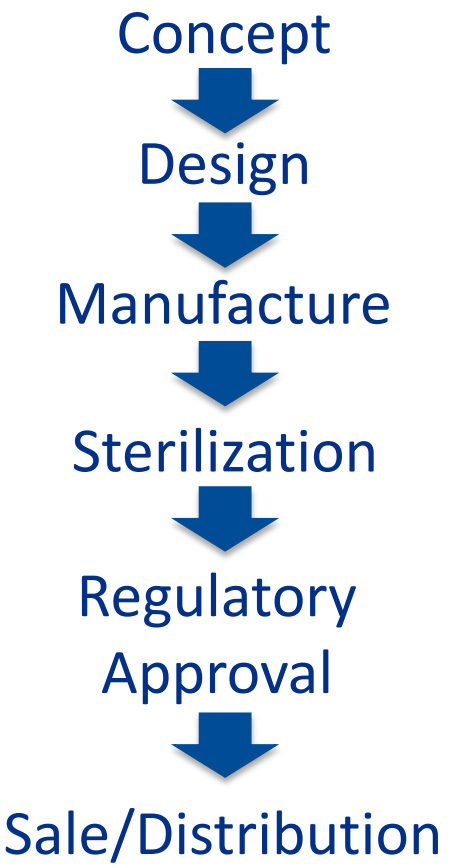
- Utilize one of Fermilab's strengths/core capability
  - Accelerators
  - Accelerator Technology
    - Vacuum
    - Cryogenics (low temperatures)
    - RF
    - Etc.
  - Detector Technology
  - Computing, particularly big data
- Fermilab must have a unique capability that is not available elsewhere in industry
  - Or is only available from a competitor

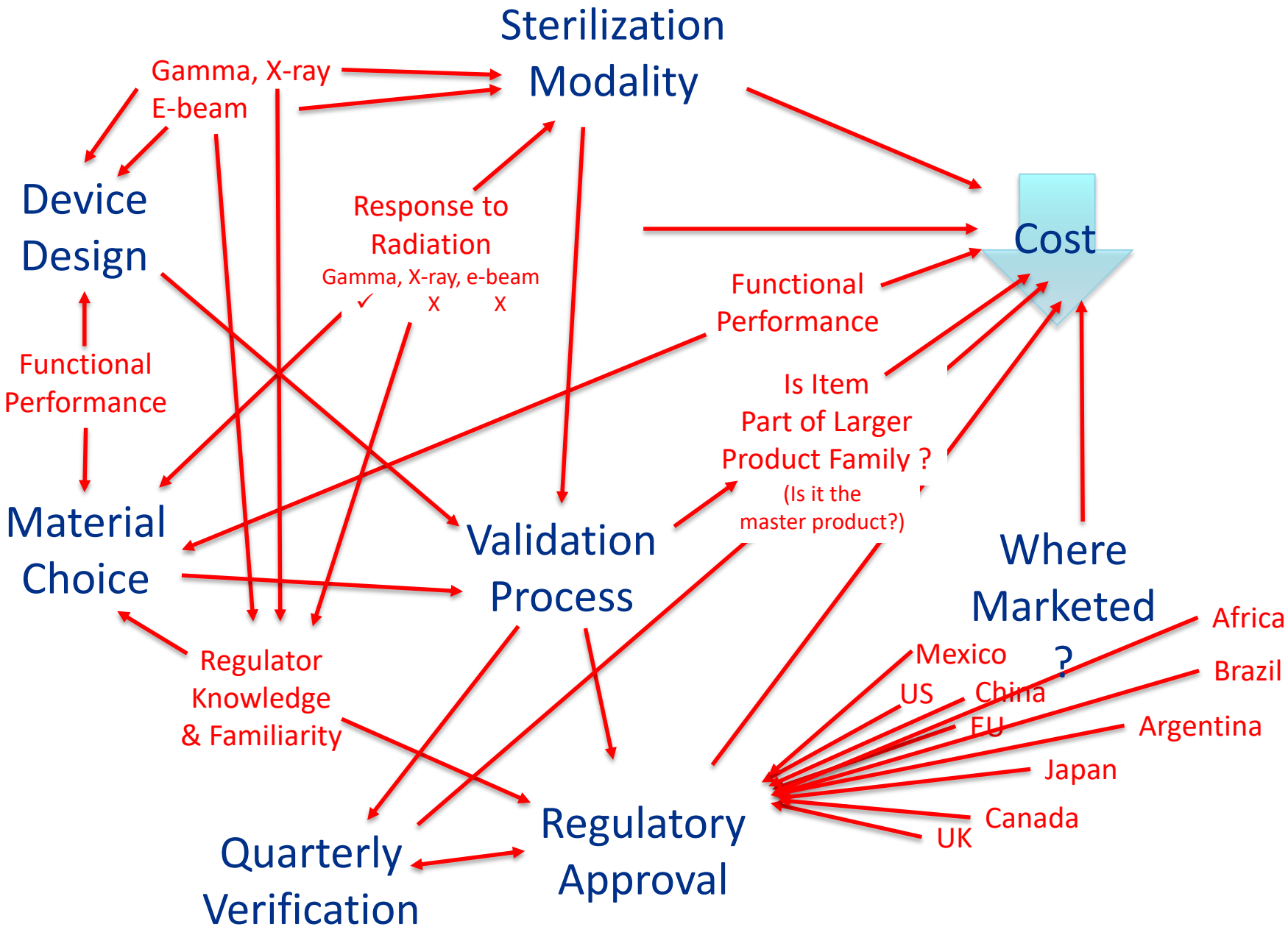
Why is IARC (Fermilab) interested in Medical Device Sterilization?

- Conversation and presentation at IMRP – 2016 (Vancouver)
  - Mention of in-line sterilization
- Presentation attended by NNSA
  - Accelerator-driven Medical Sterilization to Replace Co-60 Sources
    - lss.fnal.gov/archive/2017/pub/fermilab-pub-17-314-di.pdf
- Subject Matter Expert for upcoming White Paper
  - Non-Radioisotopic Alternative Technologies

Simple Assumptions

- Regulation is the problem
  - Reducing or modifying will accelerate switching of modalities
- Devices are simple
  - A syringe
- Each device stands on its own
  - Syringe, clamp, suture
- A single person or group has a comprehensive view from conception to sale
- Choice of sterilization modality is a discrete point in decision making




Sterilization Modality
Gamma, X-ray
E-beam
Device Design
Response to Radiation
Gamma, X-ray, e-beam
✓ X X
Cost
Functional Performance
Functional Performance
Is Item Part of Larger Product Family ?
(Is it the master product?)
Material Choice
Validation Process
Where Marketed ?
Africa
Brazil
Mexico
US
China
EU
Argentina
Japan
Canada
UK
Regulator Knowledge & Familiarity
Quarterly Verification
Regulatory Approval

Facilitator

- Made a connection with Baxter, international headquarters nearby
- What can we do?
- Provide a neutral environment to see if we can help develop collaborations on a non-competitive topic
  - i.e. Safety – specifically, the sterilization of medical products using ionizing radiation using accelerators
  - Develop more resiliency in the system
- Focus of this workshop is on radiation sterilization
  - But we won't completely ignore EO
  - It is part of the sterilization environment

Feedback

- We want to hear what you are thinking
  - Pre and post surveys
  - Questions during panels
    - Use note cards, pass to ends
    - Mics for interactive questions
  - Topical discussions during lunch
  - Breakout sessions
  - Sticky notes
    - Use at any time, place on easels during breaks
- Final report
  - NNSA & FDA participation
    - Intend to report on the essence of conversations and discussions
    - Not our intention to put anyone on record

Format

- Four Themes
  1. You Are Here: Current Paradigms and Drivers in Medical Device Sterilization
  2. The Right Tool for the Right Job: Considerations for choosing your Sterilization Method
  3. Flipping the Switch: Moving from Planning to Implementation
  4. Accelerating the Path Forward: Prioritizing Needs, Opportunities, and Points for Collaboration

Format

- Each theme is led by 1 or two presentations
- Followed by moderated panel discussion
  - Questions during panels
    - Use note cards, pass to ends
    - Mics for interactive questions
- Sticky notes
  - Use at any time, place on easels during breaks

Thank you

- Attendees
- Presenters and Panelists
- Moderators
  - Kyrstan Polaski
  - Jodi Lieberman
- Organizing committee
  - Mark Pasmore
  - Debbie Cotton
  - John Williams
  - Cherri Schmidt
  - Thomas Kroc
- Fermilab and DOE site office