U.S. Department of Energy

Isotope Program Overview

Presentation to
DOE/NSF Nuclear Science Advisory Committee

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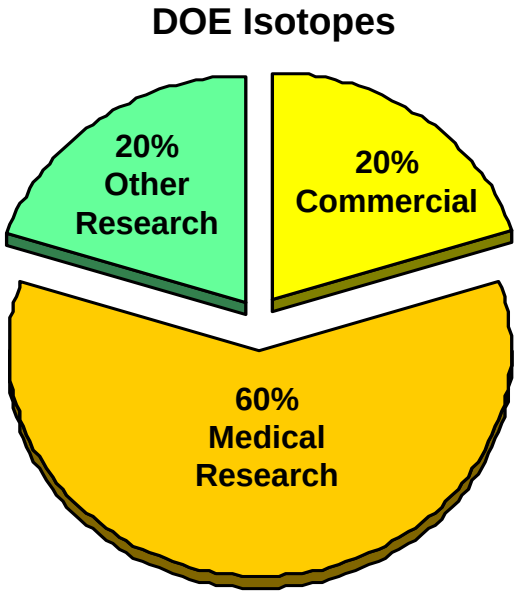
Mission of DOE's Isotope Program

- Produce and sell radioactive and stable isotopes, associated byproducts, surplus materials, and related isotope services.
- Maintain the infrastructure required to supply isotope products and related services.
- Served over 160 customers in FY 2007 and made 484 shipments, most to universities and hospitals



Why We Provide These Services

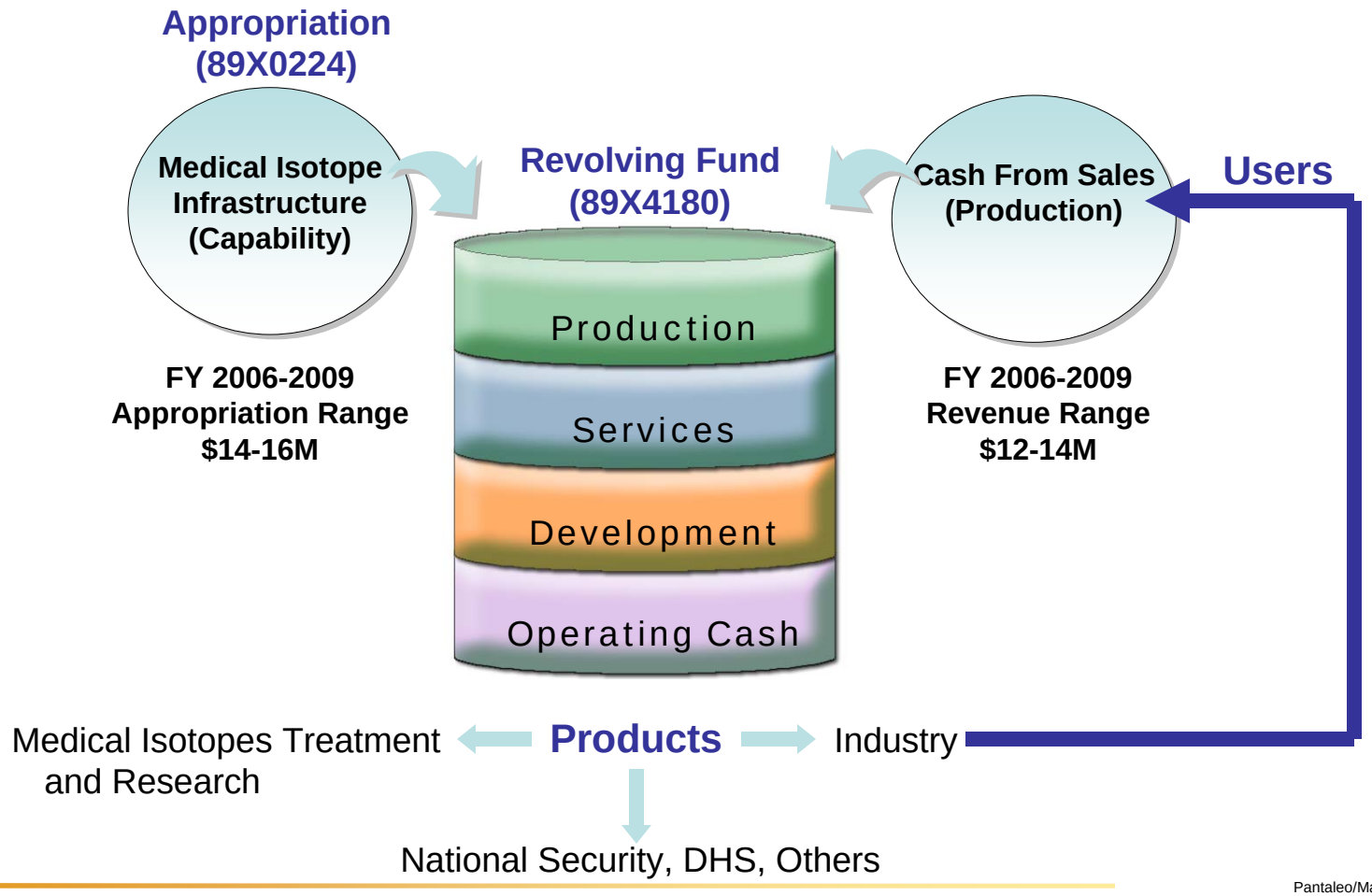
- **Since the 1940's, substantial dependency has been built around the use of the Department's isotope product and services.**
- **Vital research, biomedical, homeland security, and industrial applications – such as heart imaging, explosive detectors, climate tracers.**
- **Approximately 12-15 million diagnostic procedures and several hundred thousand therapeutic treatments conducted annually.**
- **Unique facilities, such as large reactors, accelerators, and isotope processing hot cells, are not available elsewhere.**

Program Authority

- Atomic Energy Act of 1954, sections 31,53,54, and 81.
- In 1989, the Department requested and Congress established the Isotope Program as a single point at DOE headquarters for oversight of the Department's isotope activities.
- Public Law 101-101, as modified by Public Law 103-316 created the Isotope Production and Distribution Program Fund (a revolving fund) and allow prices charged for products and services to be based on production costs, market value, U.S. research needs and other factors.
- The annual appropriation and revenues from isotope sales are deposited in the fund. Isotopes are priced such that the research customers pay cost of production and commercial isotopes are sold at full-cost recovery.

DOE's National Isotope Supply Program

- Isotope Program operates under a revolving fund and is audited annually.
- Program costs are financed by two resources: appropriation and revenue.



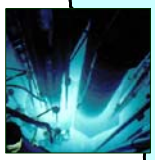
Short Term Goals

- To meet the growing isotope demand, the Isotope Program will:
  - Continue to maintain isotope processing facilities to include meeting the FDA's requirements for current Good Manufacturing Practices (cGMP);
  - Work with universities and other private sector isotope producers to increase research isotope availability;
  - Develop at least two new isotope processing techniques as requested by researchers;
  - Continue to import irradiated targets from foreign suppliers to enhance supply;
  - Continue sales from large inventories – stable isotopes, long-lived radioisotopes such as curium-244;
  - Address the recommendations of the National Institutes of Health study on the "State of Nuclear Medicine"; and
  - Make limited investments to university infrastructure that can achieve production at lower cost than the national laboratories of small quantities of medical research isotopes.

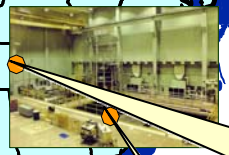
Production Locations

Pacific Northwest
Stronium/Sr-90
- Parent for Y-90

Idaho
Iridium/Ir-192 - Industrial nondestructive examination
Cobalt-60/Co-60 - Sterilization of surgical equipment and blood







Brookhaven - BLIP:
Copper/Cu-67 - Antibody labeling for cancer therapy and imaging
Germanium/Ge-68 - Calibration sources for PET equipment; Antibody labeling
Strontium/Sr-82 - Cardiac imaging

Oak Ridge - Stable Isotopes Inventory:
Calcium/Ca-42 - Calcium retention studies
-43 - Nutrition
-44 - Bone growth
-45 - Nucleosynthesis
-48 - Nuclear physics
Strontium/Sr-88 - Reactor targets for Sr-89 (used in bone cancer therapy and labeling of monoclonal antibodies)
Thallium/Tl-203 - Targets for Tl-201 production in accelerators (Ti-201 used in cardiac imaging)

High Flux Isotope Reactor/Inventory:
Selenium-75 - Industrial nondestructive examination
Nickel-63 - Explosives detection
Californium-252 - Industrial source
Tungsten/Tn-188 - Cancer therapy
Actinium/Ac-225 - Cancer therapy

UC Davis/McClellan:
Iodine/I-125 - Prostate cancer therapy

Trace Life Sciences
Copper/Cu-67 - Cancer therapy

Los Alamos - LANSCE:
Aluminum/Al-26 - Research: Alzheimers disease Acid rain
Copper/Cu-67 - Antibody labeling for cancer therapy and imaging
Germanium/Ge-68 - Calibration sources for PET equipment; Antibody labeling
Strontium/Sr-82 - Cardiac imaging

Missouri University Research Center:
Lutetium-177 - Treatment of ovarian and colon cancer
Holmium-166 - Treatment of multiple myeloma and rheumatoid arthritis
Phosphorus-32 - Used in SPECT imaging

Savannah River – Helium-3 Production:
Helium-3 - Helium-Lithium and Helium-Neon lasers
- Fuel source for fusion reactors
- Research: Properties of super fluids studies

Brookhaven Linac Isotope Producer (BLIP)

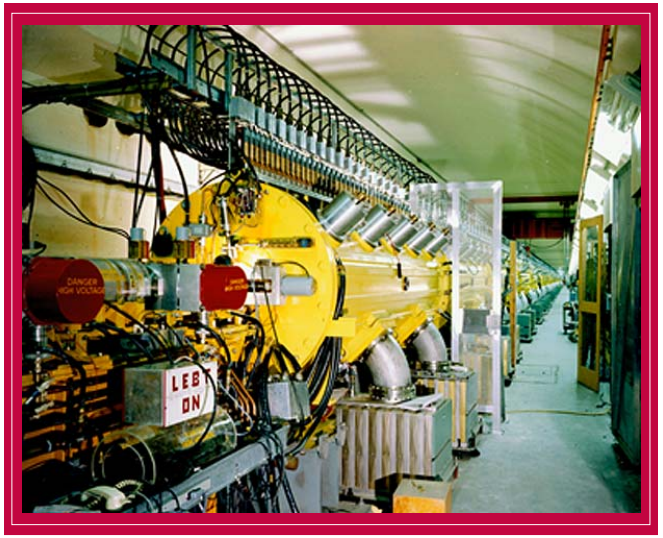
Brookhaven National Laboratory

Major Medical Isotopes and Their Applications

Copper-67	**Antibody labeling for cancer therapy**
Germanium-68	**Calibration sources for Positron Emission Tomography equipment, antibody labeling**
Strontium-82/ Rubidium-82	**Cardiac imaging**

Advantages of BLIP for isotope production

- High energy beam with flexible access
- Well-equipped hot cell facility
- Target insertion and retrieval



Isotope Production Facility (IPF)

Los Alamos National Laboratory

Medical Isotopes and Their Applications

Germanium-68	**Calibration sources for Positron Emission Tomography equipment, antibody labeling**
Arsenic-73	**Biomedical Tracer for Arsenic Uptake**
Strontium-82/ Rubidium-82	**Cardiac imaging**

Advantages of IPF for isotope production

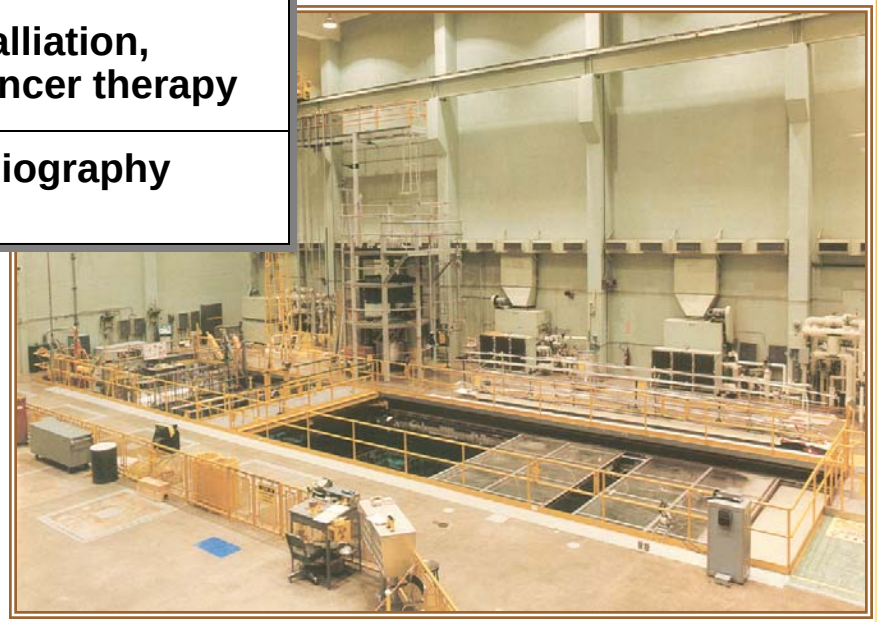
- High energy beam – not available in the private sector
- State-of-the-art facility – target insertion and retrieval
- Well-equipped and staffed Hot Cell Facility
- Available 30-40 weeks per year
- Will enhance short-lived isotope supply

High Flux Isotope Reactor (HFIR)

Oak Ridge National Laboratory

Medical Isotopes and Their Applications

Californium-252	**Cancer therapy**
Nickel-63	**Gas sensing devices**
Tungsten-188/Rhenium-188	**Bone pain palliation, from liver cancer therapy**
Selenium-75	**GAMMA Radiography sources**



Advantages of HFIR for isotope production

- High neutron concentration
- Easy access through hydraulic tubes
- Several hot cell facilities

Future

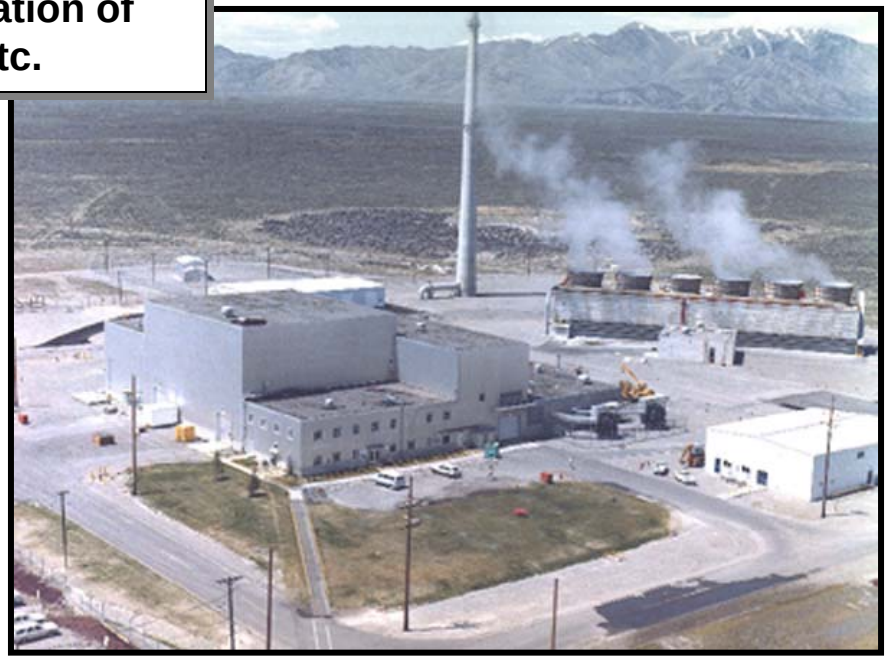
- Capacity exists to produce many more isotopes

Advanced Test Reactor (ATR)

Idaho National Laboratory

Isotopes Produced and Their Applications

Cs-131	**Brachytherapy (seed implants)**
Co-60	**Irradiators for sterilization of medical equipment, etc.**



ATR Advantages

- Large reactor - moderately high flux
- Many irradiation positions available
- Hot cell facilities

Future

- In FY 2008, install hydraulic tube for short-lived isotopes

Lutetium-177 and Tungston-188

Chemical and Materials Laboratories

Oak Ridge National Laboratory

Stable Isotope Services

Chemical physical forms	Metal and ceramic powder
Pyrochemical conversion – oxides to high purity metal	Wire rolling/swaging (hot or cold)
Drop casting	Target fabrication

These laboratories are available to provide unique stable services and dispense over 200 different isotopes in a wide variety of chemical and physical forms.

Materials Laboratory

Isotope Development

- Lutetium-177 high specific activity used in peptide radio-labeling emits a low beta energy, which reduces radiation side effects and produces a tissue-penetration range appropriate for smaller tumors, colon, bone, liver, lung cancer.
- Barium-131 is the parent isotope in a Ba-131/Cs-131 generator, an alternative used for the manufacture of seed implants used for prostate cancer therapy.
- Yttrium-86 is a positron emitter which can be used for PET imaging prior to cancer immunotherapy with yttrium-90. Yttrium-86 labeled tumor-seeking monoclonal antibodies (Mab) can be used for evaluating effective tumor uptake and radiation dose.

A Few Key Isotopes Shipped

Isotope	Half Life	Maximum Quantity Shipped in Type A	Produced	Application
Californium-252	2.645 yr alpha	.02 Ci	Reactor	Neutron sources cancer therapy
Cadmium-109	32.2 yr gamma	27 Ci	Both reactor accelerator	X-ray instrument calibration
Cobalt-60	5.27 yr gamma	10.8 Ci	Reactor	Sterilization
Strontium-82	25-day positron	5.41 Ci	Accelerator	Cardiac imaging
Tungsten-188 Treatment	69-day beta-gamma	5.41 Ci	Reactor	Cancer

FY 2009 Investments

- Insufficient dedicated isotope production capabilities to permit year-round isotope production.
- Aging facilities and equipment.
- Isotope research and development needs to be reestablished. That will respond to the need for new isotope products and support faster, better, more economical methods of isotope production.
- No lead sponsor for large commercial isotopes (americium-241, californium-252).
- Batch pricing caused by budget restrictions is impacting research.
- Researchers are forced to pay for the entire isotope batch.
- No guarantee that research isotopes will be produced when requested.
- Reduced isotope portfolio (FY 2002).

For Isotope Information

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