Isotope Production-Related Studies at the National Academies

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THE NATIONAL ACADEMIES
Advisers to the Nation on Science, Engineering, and Medicine

Presentation Outline

- Organization information
- Recent studies
  - Advancing Nuclear Medicine Through Innovation
  - Radiation Source Use and Replacement
- Ongoing study
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Organization Information

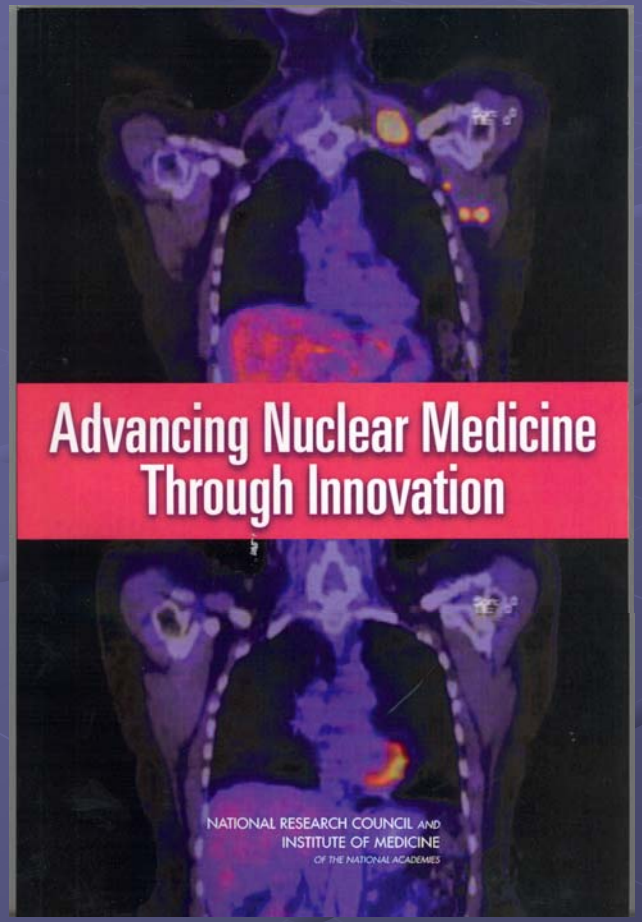
The National Academies

- National Academy of Sciences (NAS)
- National Academy of Engineering (NAE)
- Institute of Medicine (IOM)
- National Research Council (NRC)

Congressionally chartered (1863); private & nonprofit

Studies carried out by committees of outside experts who serve pro bono

Advancing Nuclear Medicine Through Innovation



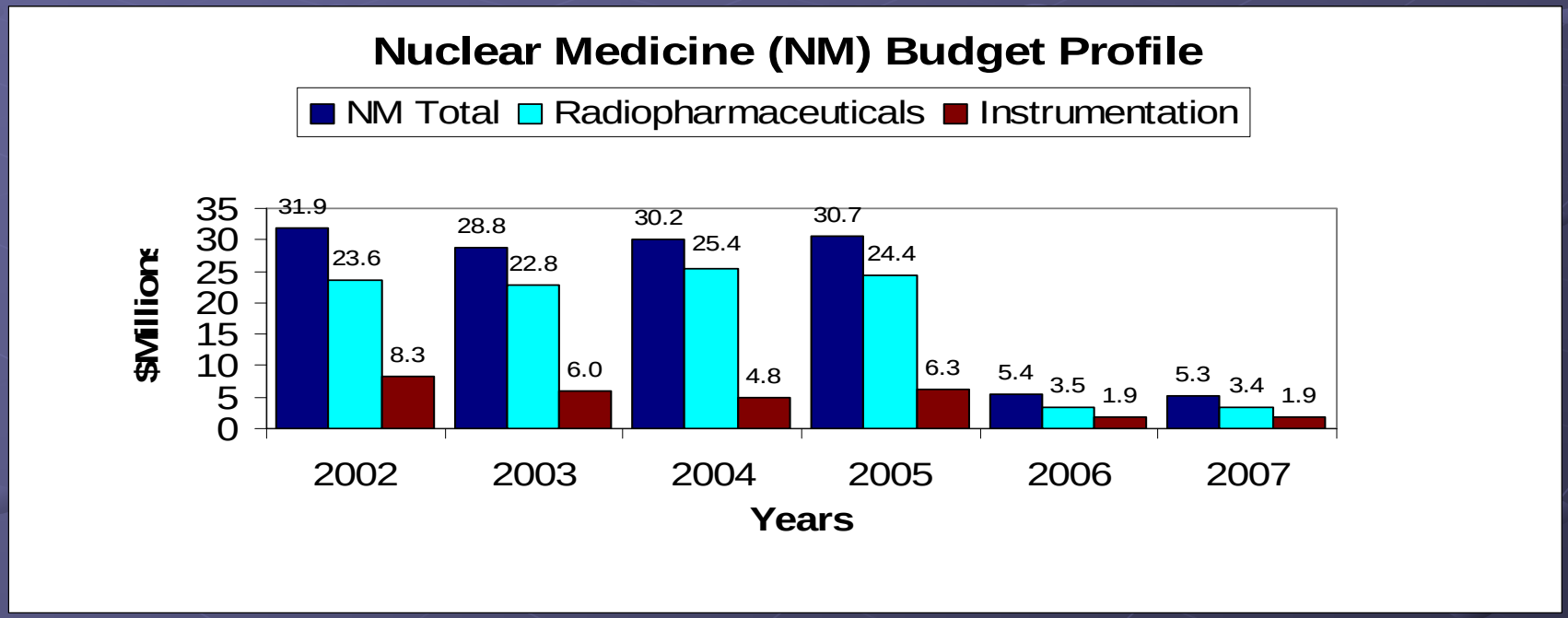
- Jointly sponsored by DOE and NIH
- Final report published in 2007
- Can be read online at http://www.nap.edu/catalog.php?record_id=11985

Background

Basic nuclear medicine research has been funded through the Medical Applications and Measurement Sciences Program within DOE-SC (Office of Biological and Environmental Research)

Background (II)

Funding for the program was cut by 85% ($23M) in fiscal year 2006



SOURCE: DOE-OBER

Background (III)

- This budget cut was the result of an effort by the Office of Management and Budget to reorganize and move the program from DOE to NIH
- DOE and NIH requested that the National Academies perform a state of the science review to inform a possible program reorganization

Study Task (Abridged)

The National Academies will perform a "state of the science" review of nuclear medicine:

1. Future needs for radiopharmaceutical development

2. Future needs for computational and instrument development

3. National impediments to the efficient entry of promising new radiopharmaceutical compounds

4. Impacts of shortages of isotopes and highly trained radiopharmaceutical chemists and other nuclear medicine scientists on nuclear medicine basic and translational research, drug discovery, and patient care

Study Task (II)

The National Academies should examine the Medical Applications and Measurement Sciences Program and make recommendations to improve its research and isotope impacts on nuclear medicine. These recommendations should address both research thrusts and facility capabilities but should not address program management issues.

Examples of Emerging Opportunities

- Understand the metabolism and pharmacology of new drugs and assess their efficacy
- Develop targeted radionuclide therapeutics to individualize treatment for cancer
- Develop higher resolution and hybrid (e.g., PET/MRI) imaging instruments
- Improve radionuclide production, chemistry, and automation

Selected Findings

- Loss of a Federal commitment for nuclear medicine research
  - DOE-NE's Isotope Program is not meeting the needs of the research community because it is not adequately coordinated with NIH or DOE-OBER
- Inadequate domestic supply of medical radionuclides for research
- Shortage of trained nuclear medicine scientists

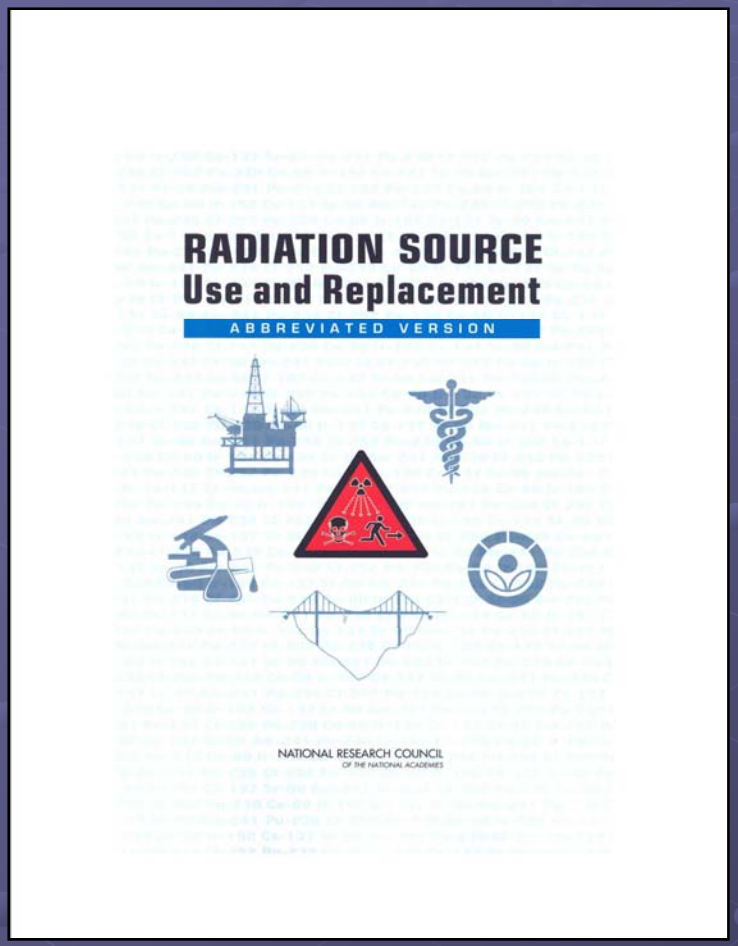
Selected Recommendations

- **Enhance the Federal commitment to nuclear medicine research**
  - **Consider reinstating support for the DOE-OBER program**
  - **Improve coordination between DOE and NIH**
  - **Develop a nuclear medicine program strategic plan with broad input**
- **Improve domestic medical radionuclide production**
  - **Consider building a dedicated accelerator and upgrading an existing research nuclear reactor**

Selected Recommendations (II)

- **Train nuclear medicine scientists:**
  - **Consider convening expert panels to identify the most critical national needs and determine how to develop appropriate curricula to train the next generation of nuclear medicine scientists**
  - **Provide additional, innovative training grants**

Radiation Source Use and Replacement



- Congressional Request: 2005 Energy Policy Act
- Sponsored by the Nuclear Regulatory Commission
- Final report published in 2008
- Can be read online at http://www.nap.edu/catalog.php?record_id=11976

Background

- Approximately 5,000 devices containing nearly 55,000 Category 1 and 2 (“high-risk”) radiation sources are licensed for use today in the United States
- The devices are used for applications that are important to society: cancer therapy, sterilization of medical devices, irradiation of blood for transplant patients and of laboratory animals for research, non-destructive testing of structures and industrial equipment, and exploration of geologic formations to find oil and gas deposits

Study Task (Abridged)

The principal task of this study is to review the current industrial, research, and commercial (including medical) uses of radiation sources to identify uses for which:

(1) the radiation source can be replaced with an equivalent (or improved) process that does not require the use of radioisotopes or

(2) the radiation source can be replaced with another radiation source that poses a lower risk to public health and safety if it is involved in an accident or used in a terrorist attack

The study should explicitly consider technical and economic feasibility and risks to workers from such replacements

Selected Report Messages

- Applications of radionuclide sources are important and beneficial; replacements should have acceptable performance
- Area denial and its costs must be considered in the evaluation of security risks from these sources, not just deterministic effects
- Non-radionuclide replacements exist for nearly all radionuclide sources. Not all of these are practical or economically attractive now, but most are improving
- Need to take actions to implement near-term replacement of cesium chloride sources
- Need to adopt policies that provide incentives to replace other Category 1 and 2 sources

Selected Recommendations

- The U.S. Government (USG) should implement options for eliminating Category 1 and 2 cesium chloride sources from use in the United States and, to the extent possible, elsewhere
  - i. Discontinue licensing of new cesium chloride irradiator sources
  - ii. Put in place incentives for decommissioning existing sources
  - iii. Prohibit the export of cesium chloride sources to other countries, except for purposes of disposal in an appropriately licensed facility
- The USG should adopt policies that provide incentives (market, regulatory, or certification) to facilitate the introduction of replacements or reduce the attractiveness and availability of high-risk radionuclide sources

Medical Isotope Production without Highly Enriched Uranium

- Congressional Request: 2005 Energy Policy Act
- Sponsored by DOE-National Nuclear Security Administration (DOE-NNSA)
- Mandate reflects an effort by Congress to strike a balance between two important national interests:
  - Availability of reasonably priced medical isotopes in the United States
  - Proliferation prevention

Study Task

Two part study task:

- Part 1 mandated in Energy Policy Act of 2005
- Part 2 negotiated between National Academies and DOE-NNSA

Study Task: Part 1

1. Feasibility of procuring supplies of medical isotopes from commercial sources that do not use HEU
2. Current and projected demand and availability of medical isotopes in regular current domestic use
3. Progress being made by DOE and others to eliminate all use of HEU in reactor fuel, reactor targets, and medical isotope production facilities
4. Potential cost differential in medical isotope production in reactors and target processing facilities if the products were derived from production systems that do not involve fuels and targets with HEU

Feasibility Definition

Congress defined LEU production to be feasible if:

> "the average anticipated total cost increase from production of medical isotopes … without use of HEU is less than 10 percent"

NOT specified by Congress:

- Process point at which feasibility is to be measured: e.g., point of production versus patient
- Time scale for feasibility determination

Study Charge: Part 2

If the National Academies determines that the procurement of medical isotopes from commercial sources is not feasible … it should estimate the magnitude of the cost differential and identify additional steps that could be taken by DOE and medical isotope producers to improve the feasibility of such conversions. In estimating the magnitude of cost differentials, consideration should be given to facilities utilized by both large and small producers. The National Academies should also identify any reliability of supply issues that could arise as a result of such conversions

Comments

- Report findings and recommendations cannot be disclosed until the report it has cleared National Academies review
- Report will likely provide:
  - “Feasibility” estimates at several points in the isotope supply chain
  - Assessment of the technical feasibility of conversion to LEU targets by current producers
  - Assessment of the reliability of supply, especially in light of the recent AECL decision to discontinue work on the Maple Reactors
  - Domestic options for improving supply reliability

Contact Information

- To order reports (paper or pdf):

  www.nap.edu

- For additional information about studies:

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