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advancing molecular imaging

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National Radionuclide Production Enhancement (NRPE) Program:

Meeting Our Nation's Need for Radionuclides

The following report was prepared by the National Radionuclide Production Enhancement Task Force (NRPE Task Force) over a multi-year period and reflects the Task Force's recommendation to help meet current and future growing demand for radionuclides which are used in a rapidly growing number of diagnostic and therapeutic procedures.

The NRPE Task Force was comprised of leading American nuclear medicine physicians, scientists, researchers and radiopharmacists hailing from different professional organizations, such as D.O.E. and industry experts. Task Force was charged with not only identifying current and future needs for radionuclide production, but also charting a multi-year course of activities that Congress and the Executive Branch must take to affect a long-term solution to our Nation's radionuclide production shortage.

The following program sets out a suggested timeline of specific actions that will:

- Address the current and projected future shortfalls of radionuclides in the United States
- Be fiscally sound and responsible in both its cost assumptions and Federal budget implications; and
- Assure our Nation of a stable and secure supply of radionuclides for generations to come.

The NRPE program has been endorsed by eleven biomedical organizations (Addendum attached). For additional information, please contact:

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National Radionuclide Production Enhancement (NRPE) Program:
Meeting Our Nation's Need for Radionuclides

BACKGROUND

Nuclear Medicine is a well-established diagnostic and therapeutic discipline that uses small quantities of radionuclides (radiopharmaceuticals) to diagnose diseases and slightly greater quantities to treat diseases. The diagnostic procedures provide effective ways to gather functional, pathophysiologic as well as anatomic information that would otherwise not be available by other imaging procedures, or that may require biopsy or exploratory surgery. In addition, nuclear medicine procedures can treat certain diseases and can also determine the effectiveness of therapeutic intervention. No other existing single modality can perform all these functions. Furthermore nuclear medicine imaging procedures often identify abnormalities very early in the progress of a disease – long before many medical problems are apparent with other diagnostic tests. An estimated 16 million nuclear medicine diagnostic and therapeutic procedures are performed each year in the United States and the number of procedures has continued to grow steadily.

In imaging, the radiopharmaceuticals are detected by special types of cameras (SPECT, PET, or gamma) that are coupled with computers to provide precise pictures of the internal parts of the body being imaged. In treatment, radiopharmaceuticals go directly to the organ being treated. The amount of radiation in a typical nuclear imaging procedure is comparable with that received during a diagnostic x-ray, and the amount of radioactivity received in a typical treatment procedure is kept within safe limits.

Today, nuclear medicine procedures are essential to the management of large numbers of patients in many medical specialties, from pediatrics to geriatrics and from oncology to cardiology, neurology and psychiatry. There are nearly 100 different nuclear medicine imaging procedures current in use. Common nuclear medicine applications include diagnosis and treatment of hyperthyroidism (Graves' Disease) and thyroid cancer, cardiac stress tests to quantify heart function, diagnose coronary heart disease and determine the effectiveness of coronary artery bypass surgery and angioplasty. Other uses include bone scans to determine if cancer has spread, lung scans to diagnose pulmonary embolism and the early diagnosis of Alzheimer's disease. New and innovative nuclear medicine treatments that identify and characterize molecular targets within the body are revolutionizing our understanding of pathophysiology, genesis and approach to a range of diseases and conditions, primarily cancer and cardiovascular diseases.

Because of these new and creative nuclear medicine procedures, the Nation needs a consistent, reliable supply of domestic radionuclides for medical applications and innovative research uses. Today, new radioisotopes for diagnostic and therapeutic uses are not being developed as the national radioisotope infrastructure is chronically under funded at the Department of Energy (DOE). New and innovative nuclear medicine treatments will require reliable supplies of domestic radionuclides. Radiolabeled chemicals for proposed new treatments are critically important to the drug development process. By constraining innovative biomedical and new drug development research that relies on using radiolabeled probes, the medical community will not benefit from valuable discoveries for the diagnosis and treatment of millions of Americans.

THE PROBLEM

It is because of these successful and useful clinical applications and much needed innovative research initiatives, the demand for a variety of radionuclides is rising exponentially. However the majority of radionuclides used in daily applications today are imported on a daily basis and those required for innovative research are either available sporadically and only in limited quantities or not at all.

Today in our Nation there is only one research reactor, the University of Missouri Research Reactor) (MURR) that provides reactor-produced radionuclides for therapeutic applications. However it has a low power (10MW) that enables it to produce only relatively small quantities of radionuclides at a low specific activity (a few radioactive atoms and a much greater number of non-radioactive atoms) that limit their use.

In addition, the U.S. has no functional accelerator that can provide cyclotron-produced radionuclides needed for specific diagnostic and therapeutic applications or creative research initiatives. Commercial or university based small and large accelerators exist but they produce only limited quantities of a small number of radionuclides, primarily for routine, approved uses.

The demand for radionuclides is rising rapidly due to the blossoming therapeutic and diagnostic applications of nuclear medicine. The future of life-saving therapies and cutting edge research in nuclear medicine and molecular imaging depends on a reliable and reasonably priced supply of radionuclides. The challenge for our Nation is to secure a reliable and enhanced domestic radionuclide supply for the growing medical need of our patients and for research

There have been a dozen committees, task forces, and IOM (Institute of Medicine) reports during the past 20 years that have examined the issue of reliable radionuclide availability for biomedical research and commercial use. . With some minor differences of opinion about specific radionuclides or the rate of growth of medical radionuclide usage, these reports are generally in agreement and all identify the same trends, which are:

- Predict increased growth in radionuclide use
- Expect shortages of some major radionuclides
- Lack of a reliable supply of research radionuclides produced at a reasonable cost
- Inability of DOE to produce radionuclides at a regular interval and at a reasonable cost
- An over-dependence on non-U.S. radionuclide sources

THE SOLUTION

In order to seek a solution to this bleak situation, a task force consisting of physicians, basic scientists and industrialists hailing from different professional organizations was formed. This report comprises their recommendations, and SNM agrees that,

- Congress should realign current radionuclide resources to create a National Radionuclide Production Enhancement (NRPE) Program to improve the production of radionuclides in the United States so as to assure our Nation of a consistent and reliable supply of necessary radionuclides for research, diagnosis and therapeutic purposes.

  Major components of the National Radionuclide Program include:

  - To establish a national program to meet the national need for radionuclides. This program should develop the capability to produce large quantities of radionuclides to maintain existing technologies and to stimulate future growth in the biomedical sciences. The overall production capacity must be sufficient to insure a diverse supply of radionuclides for medical use in quantities required to support research and clinical activities. Radionuclides for clinical and research applications should be supplied reliably and with diversity in adequate quantity and quality;

  - Collaborate with medical, and industrial users to assess radionuclide needs and transfer technologies to accelerate applications;

- To facilitate the transfer of commercially viable radionuclides programs to the private sector;

- To invest in research and development to improve radionuclide production, processing, and utilization;

- To monitor continuously the radionuclide needs of researchers and clinicians;

- To establish an education program to ensure that the next generation of nuclear and radiochemists are trained and available to support the Nation's needs. (NOTE: No funds are requested for this goal but the NRPE will provide the infrastructure, personnel and environment, to support an education program.); and

- To upgrade the capability at the University of Missouri research reactor and other existing facilities that produce radioradionuclides and stable isotopes required for their production.

SPECIFIC GOALS, TIMELINE & APPROPRIATIONS REQUEST

The NRPE Task Force identified the following five specific goals, to be undertaken over a ten fiscal-year period, which will make the NRPE Program a reality. Federal resources needed in each Fiscal Year to carry out the five specific goals are noted in brackets. A total investment of $69-79 million over a ten fiscal-year-period is anticipated.

1. FY06: $6.3 million

   1.a. $6.0M Upgrade MURR (from 10MW to 20MW) to increase the quantity and quality of radionuclides for research and therapeutics. The University of Missouri will provide the additional $3 million to complete the project. (The expected outcome of this modification is given in Appendix I)

   1.b. $0.3M During this FY, funding is requested to support the work of a select committee, formed to define the optimal operating characteristics (primarily the number of generated particles, proton energy, beam current, site and management scheme) for a cyclotron-production facility that will provide radionuclides required for research and innovation. (Appendix II)

2. FY07-08: $29 million – $39 million (exact sum to be determined in FY 2006 by the select committee noted above in 1.b)

   Begin installation of a new cyclotron to be completed by 2010.

3. FY08-FY10: $3 million per year

   3.a. $1M per FY to fund research & development of small energy cyclotron target development, and research radionuclide production capability.

   3.b. $2M per FY for operating costs for the new cyclotron (noted above in 2)

4. FY10-FY15: $4 million per year.

   4a. Cyclotron continues to completion. (As is in FY07 above) R&D funding for ORNL to upgrade processing hot cells for stable supply of alpha emitting radionuclides for therapeutic applications.

4b. Research & development funding for production of alpha emitters for therapeutic uses will require $5 million per FY for four years (FY11-FY15) ($20 million total ask). (Appendix III)

5. FY16: $5 million

5a. Isotope Separator to produce enriched stable isotopes that are required as necessary as target material for production of both reactor-produced and cyclotron-produced radionuclides.

5b. Similarly, this facility will be important to maintain a stable enriched isotope inventory for research purposes. Details of this are given in Appendix IV.

* * * * *

Appendices (#I-IV Attached)

APPENDIX I

BENEFITS OF MURR UPGRADE

Each year, US physicians employ radiopharmaceuticals in an estimated 16 million diagnostic and therapeutic procedures and another 100 million laboratory tests, with nearly one in three patients who are admitted to a US hospital undergoing a test or treatment that depends on radiolabeled compounds. Demand is growing and research programs involving non-commercially available radioisotopes are promising an encouraging future for improvements to health care. It is critical that there is a capability that allows continued R&D vital for translating findings into new applications for improving and extending quality of life.

While the cost of building a new reactor facility is prohibitive, relatively modest cost improvements to an existing facility can reap sizable increases in output. It is estimated that building MURR today would cost in excess of $200,000,000, not counting the legal and administrative costs to obtain the necessary licenses. However, a fraction of that, less than $10M, can upgrade MURR's operating power from 10 to ~20 MW, maximizing the leverage of Federal dollars for significantly increased production capacity and quality of radionuclides for biomedical research, drug development, clinical trials and many diagnostic and therapeutic processes.

Such an upgrade would increase production capacity not only in the reactor's flux trap but also in the surrounding graphite reflector. The flux trap is a narrow cylinder that runs through the center of the reactor's core—only so many target samples can fit into this small area and the reactor must be shut down to access these samples. The reflector, on the other hand, is a much larger area that surrounds the reactor's core—it can accommodate more samples that can be pulled at any time during the week to serve the demand. Operating at a higher power generates more neutrons in the core and reflector, boosting MURR's irradiation capability to produce the desired radionuclides in a shorter time and/or at a higher specific activity. Higher specific activity means a higher ratio of radioactive to non-radioactive atoms in the sample, which yields a more potent, effective patient dose.

MURR currently provides radionuclides for FDA-approved drugs as well as experimental drugs: samarium-153 (Sm-153) for Quadramet® to treat the pain associated with bone cancer; yttrium-90 (Y-90) for TheraSpheres™ used to treat liver cancer; holmium-166 (Ho-166) for clinical trials to treat multiple myeloma; and lutetium-177 (Lu-177), gaining global attention and currently under development and testing for various cancers in dozens of clinical trials around the world. MURR is the only US source of routine production of Lu-177, and a power upgrade will ensure a domestic supply that meets or exceeds the Nation's growing demand.

Another key radionuclide is rhenium-188 (Re-188), which is being used widely for research in a number of applications for the treatment of cancer. Re-188 is produced from tungsten-188 (W-188). The US has one source of W-188 at this time, Oak Ridge National Laboratory's High Flux Isotope Reactor (HFIR), a federal facility that by design cannot operate at the same 6 day per week, 52 weeks per year schedule that MURR has. With a power upgrade MURR can become a back-up supplier for W-188/Re-188 generators. Because production of W-188 requires double neutron capture on W-186, doubling the operating power at MURR will increase the specific activity of the W-188 by a factor of 4. This specific activity would be suitable for the preparation of generators using current technology.

APPENDIX II

THE NATIONAL NEED FOR A DEDICATED CYCLOTRON FOR RADIONUCLIDE PRODUCTION

Certain radionuclides that cannot be produced in much higher specific activity, can be produced either only or more efficiently, using high-energy cyclotrons. Currently there is no national cyclotron facility dedicated to the development and production of these radionuclides, either in sufficient quantity, with yearlong availability, or at a reasonable cost, for clinical use and for research in molecular imaging or therapy. The research community faces an ongoing shortage of such radionuclides, and as a result, the situation has fostered an ever-increasing risk of strategic dependence on foreign sources.

The U.S. Department of Energy's radionuclide program has played an important role in supplying accelerator-produced radioisotopes to U.S. researchers and industry. These isotope radionuclides have contributed significantly to the physical and economic health of the nation. However, over the years, DOE's radionuclide production capability has been severely compromised due to under-funding, changes in the operating regimes, and limited intermittent availability of current production facilities. Due to these reasons, there is an urgent need to build and operate a new dedicated accelerator (cyclotron) to ensure that the current and future national needs for medical radionuclides can be met in a reliable, affordable, and yearlong manner.

In response to this national need, we recommend that a dedicated cyclotron, with an energy and production capability higher than the current industrial cyclotrons, be built, sited, and operated using specific design criteria, as determined by an expert scientific advisory committee with the $ 0.3M funding that is being requested for FY 06. The criteria to be defined for the cyclotron will include the energy, the beam current, type and number of beam lines, and many other parameters that will be important for a continuous, reliable production and uninterrupted availability of sufficient quantities of the radionuclides to support the research and clinical needs of the biomedical user community, including multi-center clinical trials in human subjects. This cyclotron will also serve as a national resource for R&D on next-generation radionuclides and radiopharmaceuticals, and for the education/training of desperately needed future molecular imaging scientists and physicians.

The dedicated high energy cyclotron would not only enable the development of new and more effective radiopharmaceuticals for diagnostic PET and SPECT molecular imaging, but would also catalyze and advance the very promising field of radionuclide therapy of cancer and other diseases. The versatility and reliability of the dedicated high-energy cyclotron combined with its inherent safety and flexibility of operation will reposition the U.S. as a premier and meaningful contributor to future clinical research for decades to come, leading to more effective diagnosis and treatment of various oncologic, neurologic and cardiac diseases and thus to a significant improvement in the national healthcare.

APPENDIX III

BENEFITS OF α-EMITTING RADIONUCLIDES

The promise of α-emitting radioisotopes in a therapeutic setting has long been pursued and only relatively recently have landmark achievements been reached, *i.e.*, Phase I clinical trials for treatment of leukemia, lymphoma, melanoma, and glioma. However exciting these actual translations to actual clinical evaluation are, the obstacles and financial commitments traversed to reach these achievements also serve to illuminate the extremely challenging and / or forbidding situation surrounding the supply of these radionuclides that now threaten to compromise the very future of even the most fundamental of research and cancer therapy.

Pre-clinical research has clearly indicated that α-emitters clearly have promise in the treatment of cancers such as leukemia's and lymphatic diseases, metastatic disease (ovarian & breast cancer, intraperitoneal disseminated disease), and readily accessible malignancies. In addition, a significant body of evidence supports use outside traditional limitations. This includes adjuvant therapies for "clean-up" of post-surgical excision or re-section, and as a final monoclonal antibody targeted scouring of single cell disease post therapy with targeted β-emitters. Additionally, exceptionally resistant bacterial and fungal infections have been demonstrated responsiveness to targeted α-emitting radionuclide therapy.

A Phase I clinical trial for treatment with At-211 was opened and has seen some success. This radionuclide is cyclotron produced but is made by only a limited number of appropriate production sites. The commitment to maintain a dedicated production & purification facility remains outside the reach of most researchers. Additionally, while there are a significant number of medical cyclotrons across the country, the number functionally capable of producing this radionuclide are quite limited. This lack of production and availability not only compromises the ability to perform widespread pre-clinical and clinical studies, but also severely limits the fundamental understanding of this radionuclide and even the element itself.

Ac-225 and Ra-224 are available from their respective Thorium chain parents; their respective decays provide Bi-213 or Bi-212 (Pb-212). Their half-lives are suitable for shipping and the creation of generator systems that then provide Bi-213 or Bi-212 (Pb-212). A large body of research has been published pertaining to use of Bi213 or Bi-212 (Pb-212) as therapeutics and a second Phase I trial is running to treat AML (leukemia) with Bi-213 at Sloan-Kettering; a Phase I trial is ongoing in Germany to treat lymphoma while a Phase I trail has been initiated in Australia to treat melanoma. These radionuclides have received significant attention and remain actively investigated.

The major issue that compromises widespread research of these radionuclides is supply and cost. However, proven translation to clinical trials has fueled interest in this burgeoning aspect of targeted radiation therapy. Overnight, demand exceeded supply while cost has quadrupled over the past 3 years without any significant increase in supply. It is unclear how researchers can continue given current grant funding and budget conditions. Thus, demand driven by good results exceeds supply, while prices exceed reality with no suitable resolution on the horizon with a net result of driving researchers out of the field.

In order to perform real and meaningful evaluations of these exciting new therapies, there must be sufficient availability of the radionuclides at an affordable cost to carry out the size and scope of clinical trials.

APPENDIX IV

ISOTOPE ENRICHMENT FACILITY

There are currently two facilities in the world capable of production-scale enrichment of stable isotopes using the electromagnetic process.* Several other enrichment technologies exist: however, they are limited in the number of elements that can be processed while electromagnetic enrichment is applicable to all elements. One of these facilities is located at the Y-12 National Security Complex and operated by the Oak Ridge National Laboratory (ORNL) and the other is in Russia. The U.S. facility has not been in production since July 1998, but is being maintained in an operable standby condition. Both the U.S. and Russian facilities originated in the 1940s and are grossly inefficient and incapable for the stable isotope needs of the Nation.

At present, the world is relying on historic inventories of stable isotopes, both at ORNL and in Russia, and some level of continuing enrichment in Russia. The inventories of many isotopes are being depleted or have been exhausted. A reliable and affordable supply of stable isotopes is needed for countless R&D applications and for the production of radionuclides for commercial and medical applications. New applications for stable isotopes continue to be developed, especially in the areas of analytical chemistry and non-radioactive tracers.

Two approaches are currently being evaluated for modernized and affordable stable isotope enrichment. The first involves the procurement of a new electromagnetic separator and its installation in an existing facility at ORNL. Some years ago, a commercial, but unproven, electromagnetic separator was priced at $5 M for equipment, facility modification and installation. The present availability of this commercial unit is questionable. Also, one unit may not be able to meet production needs and additional units may be required.

A second approach involves the relocation and use of some selected, existing calutron components and the procurement of modern components to complete up to 6 modernized calutrons. These units could be operated separately or in groups to meet R&D and production needs and be located in an appropriately smaller, more economical and accessible facility at ORNL. Costs estimates for this approach are not readily available at present, but are expected to be comparable (i.e., $5M installed)

* Approximately 160 stable isotopes can only be enriched by the electromagnetic process.

ADDENDUM

BIOMEDICAL ORGANIZATIONS THAT HAVE FORMALLY ENDORSED THE NRPE PROGRAM

(as of February 8, 2005)

Academy of Molecular Imaging

Academy of Radiology Research

American Association of Physicists in Medicine

American College of Nuclear Physicians

American College of Radiology

American Medical Association

American Society of Nuclear Cardiology

Council on Radionuclides and Radiopharmaceuticals

Radiation Therapy Oncology Group

Radiological Society of North America

Society for Molecular Imaging

Society of Radiopharmaceutical Sciences

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December 20, 2004

Michael J. Welch, PhD
Chairman
NRPE Task Force
Mallinckrodt Institute of Radiology
St. Louis, MO

Mathew L. Thakur, PhD
President
Society of Nuclear Medicine
Thomas Jefferson University
Philadelphia, PA

Dear Dr. Welch and Dr. Thakur:

The AMI board has voted to formally endorse the National Radionuclide Production Enhancement (NRPE) Program, as well as work with SNM and other organizations involved to successfully achieve funding and implementation.

The AMI supports the NRPE's recommendation of a ten-year program designed to address the critical issue of current and projected future shortfalls of radionuclides in the United States in a fiscally sound manner. The implementation of the recommended program would significantly alleviate domestic reliance on imported radionuclides, assuring a stable source of these agents both for innovative research as well as for patient care.

The proposed program length of ten years shows a concern for fiscal responsibility with respect to both internal program cost assumptions and the current economic climate for federally-funded initiatives.

In sum, the NRPE Program has the fullest support of our organization.

Sincerely,

R Edward Coleman

Edward Coleman, M.D.
President, Academy of Molecular Imaging

January 7, 2005

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Mathew L. Thakur, Ph.D.
President
Society of Nuclear Medicine
1850 Samuel Morse Drive
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Dear Dr. Thakur:

The Academy of Radiology Research is pleased to endorse the National Radionuclide Production Enhancement (NRPE) program developed by the NRPE Task Force.

The Academy recognizes the importance of a stable and sufficient source of radionuclides for both clinical and research uses, particularly at a time when the demand for radionuclides is increasing. We believe that the NRPE program proposed by the Society of Nuclear Medicine and the American Nuclear Society represents a significant advance toward this goal.

I look forward to working with you to move this proposal forward.

Sincerely,

Edward C. Nagy

Edward C. Nagy
Executive Director

American Association of Physicists in Medicine

Office of the President
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December 17, 2004

Michael J. Welch, PhD
Chairman
NRPE Task Force
Mallinckrodt Institute of Radiology
St. Louis, MO 63110

Mathew L. Thakur, PhD
President
Society of Nuclear Medicine
Thomas Jefferson University
Philadelphia, PA

Dear Drs. Welch and Thakur:

The Nuclear Medicine Committee, Science Council, Professional Council and Executive Committees of the American Association of Physicists in Medicine (AAPM) have reviewed the concept of National Radionuclide Production Enhancement (NRPE) Program. The AAPM recognizes our country's need for increasing radionuclide production to meet the requirements for medical use. The AAPM fully supports the recommendations of the NRPE Task Force Report. We would encourage Congress to include sufficient support in the FY2006 budget.

The AAPM looks forward to working closely with you in the future. Please feel free to contact me at any time.

Yours truly,

G. Donald Frey, PhD
President

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Mathew L. Thakur, Ph.D.
President
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RE: NATIONAL RADIONUCLIDE PRODUCTION ENHANCEMENT (NRPE)

Dear Mathew:

I am writing on behalf of ACNP to thank you for sharing the National Radionuclide Production Enhancement (NRPE) Program report with us. The report succinctly identifies the immediate need for increased supplies of radionuclides for use by clinicians and researchers as they address the burgeoning demand for new and broader uses in diagnostic and therapeutic procedures.

ACNP is pleased to offer its formal support of the NRPE Program and fully endorses efforts to include it as a priority for Congress to address. Future advances in medicine, coupled with increased national security, will be assured by its adoption.

Sincerely,

Warren H Moore MD

Warren H. Moore, M.D.
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January 5, 2005

Mathew L. Thakur, Ph.D.
President
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1850 Samuel Morse Drive
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RE: NATIONAL RADIONUCLIDE PRODUCTION ENHANCEMENT (NRPE)

Dear Mathew:

I am writing on behalf of the American College of Radiology to extend our endorsement of the NRPE proposal to ensure the domestic availability of radionuclides for medical applications and related research. SNM is to be commended for their leadership in bringing the deliberations of the NRPE task force to this point.

A secure and reliable source of radionuclides is, indeed, critical to the patients we serve. The NRPE proposal would undoubtedly help to ensure that the needs of our patients are met, even as medical advances continue to drive the demand for radionuclides.

The ACR encourages Congress to support this initiative by making provisions in the 2006 budget.

Sincerely,

Harvey L. Neiman, MD

Harvey L. Neiman, M.D., FACR
Executive Director

cc:
James P. Borgstede, M.D., Chair Board of Chancellors
E. Stephen Amis, Jr., M.D., ACR President
Virginia Pappas, CAE, Executive Director, SNM
Hugh Cannon, Director of Public Affairs, SNM

American Medical Association

Physicians dedicated to the health of America

Michael D. Maves, MD, MBA
Executive Vice President, CEO

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March 21, 2005

The Honorable Pete V. Domenici
Chairman, Subcommittee on Energy and Water Development
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Senator Domenici:

On behalf of the physician and medical student members of the American Medical Association, I am writing to urge your support of funding to enhance radionuclide production in the United States.

Each year, an estimated 16 million nuclear medicine diagnostic and therapeutic procedures are performed in the United States and new therapies are constantly being developed. Consequently, the demand for a variety of radionuclides is climbing rapidly while the supply remains quite limited. In fact, a majority of those used in daily applications in the United States are imported. Life-saving technologies and therapies like radiopharmaceuticals require a stable and reasonably priced supply of radionuclides. The United States production capacity for radionuclides must be increased if these important technologies are to remain widely available to our patients and our nation's researchers. **We urge your support of a proposal to fund a National Radionuclide Production Enhancement Program to help create the national production capacity necessary to meet current and future needs.**

We look forward to working with you and other members of the Subcommittee on this request. Please do not hesitate to contact us if we can be of assistance on this matter.

Sincerely,

Michael D. Maves, MD, MBA

Mathew L. Thakur, Ph.D.
President
Society of Nuclear Medicine
1850 Samuel Morse Drive
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Dear Mathew:

Thank you for sharing the National Radionuclide Production Enhancement (NRPE) Program report with us. The report identifies the immediate need for increased supplies of radionuclides for use by nuclear medicine clinicians and researchers for diagnostic and therapeutic procedures. As you know, there is some relief coming for clinical applications, since GE Healthcare (formerly Amersham) is breaking ground on a cyclotron and radionuclide production facility near Chicago's O'Hare International Airport. I doubt, however, as a specific commercial endeavor, that this will significantly impact the growing needs for research in this arena.

Thus, we wholeheartedly support the goals of the NRPE Program and endorse your efforts to include it as a priority for Congress to address.

Sincerely,

Kim A. Williams

Kim A Williams MD
President
American Society of Nuclear Cardiology

CC:

Virginia Pappas, CAE
Executive Director, SNM

Hugh Cannon
Director of Public Affairs, SNM

Council on Radionuclides and Radiopharmaceuticals, Inc.

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Henry H. Kramer, Ph.D., FACNP
Executive Director

January 20, 2005

Dr. Mathew Thakur, President
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Dear Dr. Thakur,

The Council on Radionuclides and Radiopharmaceuticals (CORAR)[1] closely monitors the availability of medical radionuclides in the United States. CORAR member companies rely on this supply of medical radionuclides as raw material in the radiopharmaceutical and medical products our member companies manufacture. Any interruption of this supply could jeopardize our ability to supply the nuclear medicine industry with radiopharmaceuticals, and the biomedical research community the radionuclides they need to conduct their research. As such, we have taken a keen interest in the work the Society of Nuclear Medicine is doing on their National Radionuclide Production Enhancement (NRPE) Program. CORAR is extremely supportive of this effort, and believes SNM has put together an excellent set of recommendations.

CORAR believes the NRPE has achieved a broad consensus from members of the research and clinical practice community. NRPE's concept of a national program will help assure an even and fair allocation of resources to the country's existing national laboratories and other national resources. NRPE's recommendation to collaborate with both research and clinical users will keep the program up to date with current needs of the users. CORAR also supports the concept of privatizing radioisotope programs when appropriate. We are also supportive of the educational components built into the NRPE program, especially the proposed upgrade at the University of Missouri Research Reactor (MURR).

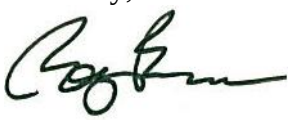
[1] CORAR is comprised of the major manufacturers and distributors of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals, and sealed sources used in therapy, diagnostic imaging, and calibration of instrumentation used in medical imaging.

CORAR also believes NRPE has done a good job coordinating its efforts with other groups interested in a continued and robust supply of medical radionuclides. These other groups include the American Nuclear Society, the Academy of Molecular Imaging, and CORAR. We believe this coordination with other groups has lead to a series of recommendations that are supported by the entire medical radionuclide community, rather than just appealing to special interest groups.

CORAR also believes that the NRPE effort has focused on the future supply for many years to come, rather than just addressing immediate needs. Some of these forward thinking proposals include the construction of a new cyclotron, supply of alpha emitting radionuclides, and the modernization of stable isotope enrichment facilities. This forward-thinking approach will address both current and future medical radionuclide needs.

The efforts of the SNM's NRPE, and that group's recommendations, have the full support of CORAR and its member companies.

Sincerely,



Roy W. Brown, Chairman
CORAR

Radiation Therapy Oncology Group

January 26, 2005

Mathew L. Thakur, Ph.D.
President
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston , VA 20190-5316

Subject: National Radionuclide Production Enhancement

Dear Dr. Thakur:

I am writing on behalf of the Radiation Therapy Oncology Group to extend our endorsement of the NPRE proposal to ensure the domestic availability of radionuclides for medical applications and related research. The Society of Nuclear Medicine should be commended for their leadership and efforts to bring the NRPE Task Force to this point.

A secure and reliable source of radionuclides is critical to patients. The NRPE proposal would help to ensure that the needs of patients are met, even as medical advances continue to drive the demand for radionuclides

The RTOG encourages Congress to support this initiative by including provisions in the 2006 budget.

Sincerely,

Walter J. Curran, Jr., M.D.
RTOG Group Chairman

RSNA | Radiological Society of North America
Founded in 1915

820 Jorie Boulevard
Oak Brook, Illinois 60523-2251
630/571-2670
FAX: 630/571-7837
www.rsna.org

January 5, 2005

Mathew L. Thakur, PhD
President
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, VA 20190-5316

RE: National Radionuclide Production Enhancement (NRPE)

Dear Dr. Thakur:

I am writing on behalf of RSNA to thank you for sharing the National Radionuclide Production Enhancement (NRPE) Program report with us. The report succinctly identifies the immediate need for increased supplies of radionuclides for use by clinicians and researchers as they address the burgeoning demand for new and broader uses in diagnostic and therapeutic procedures.

RSNA is pleased to offer its formal support of the NRPE Program and fully endorses efforts to include it as a priority for Congress to address. Future advances in medicine, coupled with increased national security, will be assured by its adoption

Sincerely,

R. Gilbert Jost, MD
Chairman of the Board

cc: Virginia Pappas, CAE
Executive Director, SNM

Hugh Cannon
Director of Public Affairs, SNM

The Society for Molecular Imaging™

Society Office
Joan Oefner, Secretariat
PO Box 19577
Stanford, CA 94309-9577 USA
Phone: 1-650-216-6621
Fax: 1-650-556-1678
joefner@molecularimaging.org

www.molecularimaging.org

January 7, 2005

Mathew L. Thakur, Ph.D.
President
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, VA 20190-5316

Dear Dr. Thakur:

Re: National Radionuclide Production Enhancement (NRPE)

On behalf of the Society for Molecular Imaging (SMI), I want to thank you for sharing the National Radionuclide Production Enhancement (NRPE) Program report with us. The leadership of the SMI wishes to extend our full support and endorsement of the NRPE Program.

As an international scientific educational organization whose purpose is to advance our understanding of biology and medicine through noninvasive in vivo investigation of cellular molecular events involved in normal and pathologic processes, the SMI understands the need for increased supplies of radionuclides for use by researchers and physicians.

Sincerely,

Thomas J. Meade, PhD
President

ETH
Eidgenössische Technische Hochschule Zürich
Swiss Federal Institute of Technology Zurich

PAUL SCHERRER INSTITUT
PSI

UniversitätsSpital
Zürich

Departement Chemien und Angewandte Biowissenschaften

Forschungsbereich Biowissenschaften

Klinik für Nuklearmedizin

Center for Radiopharmaceutical Science

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Mathew L. Thakur, Ph.D.
President
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, VA 20190-5316

USA

Your ref. Our ref. SA22/KA22 Villigen, December 27, 2004

NATIONAL RADIONUCLIDE PRODUCTION ENHANCEMENT (NRPE)

Dear Mathew

I am writing on behalf of SRS to thank you for sharing the National Radionuclide Production Enhancement (NRPE) Program report with us. The report succinctly identifies the immediate need for increased supplies of radionuclides for use by clinicians and researchers as they address the burgeoning demand for new and broader uses in diagnostic and therapeutic procedures.

SRS is pleased to offer its formal support of the NRPE Program and fully endorses efforts to include it as a priority for Congress to address. Future advances in medicine, coupled with increased national security, will be assured by its adoption.

Yours sincerely,

P.A. Schubiger, Ph.D.
Professor for radiopharmacy ETH

CC:
Virginia Pappas, CAE
Executive Director, SNM

Hugh Cannon
Director of Public Affairs, SNM