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**Leaders' Communiqué**  
**International Medical Isotope Summit**  
**June 15, 2009**  
**Toronto, Ontario**

**PREAMBLE**

1. Leaders of the nuclear medicine profession, government agencies that regulate nuclear science and technology, corporations that build nuclear facilities and manufacture medical isotopes, and other interested organizations from the United States, Canada, Europe and Australia, met in Toronto, Ontario on June 15, 2009.

**OVERARCHING PROBLEM**

2. This group agreed that the worldwide patient community is facing one of its greatest threats in modern times – the lack of access to a reliable, consistent supply of the most important medical isotopes used in the effective detection and evaluation of patients with cancers, heart and brain diseases and other disorders.

**DEFINITION OF MEDICAL ISOTOPE**

3. A medical isotope (or radioisotope or radionuclide) is a very small quantity of a radioactive material which is injected into a patient to detect, diagnose, treat or evaluate serious illnesses such as cancer and heart disease. Millions of these procedures are performed around the world each year, with approximately 70 to 80 percent of them using Technetium-99m (Tc-99m) derived from Molybdenum-99 (Moly-99 or Mo-99), which is produced in nuclear reactors.

**VALUE AND BENEFITS OF MEDICAL ISOTOPES**

4. The Tc99m isotope is attached to a variety of compounds that target specific organ systems such as the heart, or go to specific disease sites in the body after injection. Sophisticated imaging devices are then used to pinpoint the exact location of the disease and track its biologic activity. The results of these tests better inform doctors on the state of a disease in individual patients and help identify the best treatment, as well as measure and monitor response to treatment.

**LIMITED NUMBER OF REACTORS**

5. The Leaders are concerned that the vast majority of the worldwide supply of Mo-99 is produced in nuclear facilities located in only six countries: Australia, Belgium, Canada, France, South Africa and The Netherlands. With approximately 80 nations using Mo-99, and the United States consuming nearly one-half of the worldwide Mo-99 supply, it is clear that too many demands are being placed on too few facilities. Until recently, two reactors – the Chalk River facility in Canada and the Petten facility in The Netherlands – each produced approximately one-third of the world's supply of Mo-99. The current shutdown of the Chalk River facility is currently having a major impact on medical care throughout the world. Now that Canadian Prime Minister Stephen Harper has announced

that "Canada will be out of the business" of making medical isotopes within the next decade, the situation is far more urgent.

#### AGING REACTORS

6. The Leaders are troubled that the average age of these reactors is 45 years, with the oldest being over a half-century (52 years) old. These aging reactors are showing increasing signs of fatigue, becoming susceptible to power failures, leaks and other systemic problems that disrupt the production of Mo-99. Despite extensive efforts to maintain and modernize these facilities, they are simply too old and too undependable to keep up with the growing demand for medical isotopes and, therefore, can no longer be relied on as the sole sources of Mo-99.

#### IMPACT ON PATIENTS

7. Each year more than 20 million people in the US, two million in Canada, 10 million in Europe, and 14 million in the rest of the world benefit from nuclear medicine tests involving medical isotopes. The greatest concern is that patients around the world will not receive the vital testing they need to detect and treat life-threatening diseases at the earliest possible stage. Just as early detection increases the likelihood of better outcome or survival, delayed testing results in delayed treatment, putting the patient at unnecessary risk, and often increases the complexity, risk and cost of treatment when it is eventually started.

#### ENVIRONMENTAL IMPACT

8. The Leaders recognize that the potential risk of contaminating the atmosphere and groundwater rises in proportion to the fragility of these aging reactors. While there have been no life-threatening incidents at any of these reactors, it would be unwise to tempt fate longer than necessary by pushing reasonable limits for each facility. It is disturbing that the Chalk River facility in Ontario, Canada, has experienced three heavy-water leaks in two years, resulting in shutdowns lasting a total of four months. Given that one-third of the worldwide supply of Mo-99 has come from Chalk River alone, such disruptions are no longer tolerable.

#### 9. ECONOMIC IMPACT

The group acknowledges that many jobs are at stake, not only at the nuclear facilities that make Mo-99, but at the commercial radiopharmacies and nuclear pharmacies that distribute these agents to hospitals and clinics and ultimately at the sites where the patients are cared for. In the U.S. alone, there are about 500 commercial nuclear pharmacies, many of which are in small towns, employing thousands of support personnel. The jobs of thousands of nuclear medicine technologists and physicians are also at stake. Eighty percent of this \$1 billion industry is Technetium-based, so any interruption in the supply of Moly-99 has a potentially huge adverse economic impact on workers around the world.

#### SECURITY CONCERNS

10. Because Mo-99 is currently produced primarily using highly-enriched uranium-235 (U-235), the same material used to produce nuclear weapons, the Leaders are well-aware of

the security ramifications related to the use of U-235 in most of these reactors. They further recognize that we live in an age where terrorism is a very real threat to peace-loving people everywhere, and that public safety is equally as paramount as well as the patients' needs as it relates to the handling of these radioactive materials by all stakeholders. In addition to ensuring the effective safeguarding of HEUs and their by-products, there must be a systematic and orderly transition from HEUs to less volatile materials, such as low-enriched uranium.

## OUR COMMITMENT

In light of these realities, the Leadership assembled reaffirms their individual commitment and collective resolve to work aggressively to find a viable solution to the worldwide medical isotope shortage crisis as quickly as possible. Therefore, it is Resolved:

### CHALLENGE TO POLITICAL LEADERS

- A. We call on the U.S. Congress, Canadian Parliament, European Parliament, and all relevant legislative bodies around the world to appropriate the necessary funding to build new medical isotope production facilities, as well as update existing facilities to ensure that they remain safe and reliable.
- B. We encourage lawmakers to support the orderly transition from highly-enriched uranium (HEU) to low enriched uranium (LEU) within a timeframe sufficient to maintain an adequate supply of Tc-99m and to avoid an undue burden on producers and patients.
- C. We urge lawmakers to make research in the basic science of medical isotope production a top funding priority. Further, coordination of these efforts to avoid duplication is important.

### CHALLENGE TO REGULATORS

- D. We call on regulators that oversee nuclear issues, energy, health care, medical devices and pharmaceuticals to work in close collaboration with producers, scientists, physicians and others to ensure a clear pathway, free of unreasonable and cumbersome bureaucratic obstacles, so that new and improved facilities can become operational in a timely fashion.

### CHARGE TO HEADS OF STATE

- E. We ask the heads of state to demonstrate their commitment to true health care reform by acting decisively to support efforts, as appropriate, to modernize medical isotope production facilities around the world.

### CHALLENGE TO INDUSTRY

- F. We call on the builders and operators of nuclear facilities and the companies that produce and distribute medical isotopes to invest more in the future of their

companies by doing whatever it takes to provide patients around the world with a stable, predictable supply of medical isotopes. We believe putting the interest of patients first is one of the best investments we can all make.

#### CHARGE TO MEDICAL COMMUNITY

- G. The medical community must work together with regulators and industry to optimize the utilization of resources during periods of limited supply of Mo-99.
- H. We invite physicians, researchers, technologists, nurses, hospitals, clinics and other providers in the continuum of care to contact their respective lawmakers and regulators to take bold, decisive action to restore public confidence in the world's medical isotope production facilities.

#### PLEDGE TO MAINTAIN DIALOGUE

- I. We are determined to meet quarterly to review progress on our commitments and renew the sense of urgency to resolve the medical isotope shortage crisis, both in the short term and long term.

By acting together to fulfill these pledges in a spirit of public-private partnership, we are confident that we can lift the world out of this serious medical crisis and prevent such dangerous disruptions from recurring in the future.

Signed,

SNM (Society of Nuclear Medicine)

NEI (Nuclear Energy Institute)

Other signatories to follow