



Mo-99

INTERNATIONAL SYMPOSIUM

VIENNA, AUSTRIA • OCTOBER 5-7, 2022



Wednesday, October 5

Registration 4:30-6:00 pm, Vienna Marriott Hotel, Parking 12a (Floor 1, Foyer II)

Welcome Reception: 6:00 – 8:00 pm, Ballrooms A & B

#	Session Title	Time	Topic	Presenter	Organization/ Country
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Thursday, October 6

Meeting Room: IAEA C-Building (Fourth Floor) Board Room C

1	Opening Plenary Session: Supporting a Reliable, Non-HEU Mo-99 Supply Session Chair - Christopher Landers	9:00 am	1. IAEA Deputy Director General Opening Remarks	DDG Mikhail Chudakov	IAEA
		9:15 am	2. U.S. Mission Opening Remarks	Amb. Laura Holgate	UNVIE / USA
		9:30 am	3. DOE/NNSA Opening Remarks	Jeff Chamberlin	NNSA / USA
		9:45 am	4. IAEA Staff Opening Remarks	John Dewes	IAEA
10:00 am Self-Hosted Refreshment Break					
2	Perspectives from Current Global Mo-99 Producers Session Chair - Ira Goldman	10:30 am	1. Ending HEU in Mo-99 Production	Brett Cox	NNSA / USA
		10:50 am	2. Reflections on Five Years of LEU-Based Production of Medical Radionuclides	Roy Brown	Curium / USA
		11:10 am	3. All LEU Mo-99 Production Experience	Andile Ntlokwana	NTP / South Africa
		11:30 am	4. Achievements of the IRE LEU Conversion Program	Valery Host	IRE / Belgium
11:50 pm Lunch Break					
3	North American Mo-99 Production Projects Session Chair - Max Postman	1:20 pm	1. Update on Domestic Production of Mo-99	James Harvey	NorthStar / USA
		1:40 pm	2. New Infrastructure for Neutron Based Medical Isotope Production	Greg Piefer	SHINE / USA
		2:00 pm	3. Mo-99 Production - Neutron Capture-Based Production via Power Reactor and Potential Market Penetration	Andrew Lukomski	Laurentis / Canada
		2:20 pm	4. Niowave's U.S. Production of Mo-99 and other Fission Products without a Nuclear Reactor	William Peters	Niowave / USA
2:40 pm Break for Poster Session, Refreshments Provided					
4	Poster Session	2:40 - 4:10 pm	1. The Decay Vendor: A Stochastic Model for Medical Radioisotope Supply Chains	Tiffany-Thao Nguyen	University of Luxembourg
			2. NEXT Lab: Mission, Achievements, and Mo-99 Interest	Diego Zometa	NEXT Lab / USA
			3. Argonne National Laboratory Technical Support for Non-HEU Mo-99 Production	M. Alex Brown, David Bettinardi, Sergey Chemerisov, Peter Tkac, Anna Servis	ANL / USA
			4. Los Alamos National Laboratory Technical Support for Non-HEU Mo-99 Production	Bhavini Singh, Eric Olivas, Alexander Wass, Keith Woloshun	LANL / USA
			5. Oak Ridge National Laboratory Technical Support for Non-HEU Mo-99 Production	Jorge Navarro, Nolan Edward Goth	ORNL / USA
			6. Pacific Northwest National Laboratory Technical Support for Non-HEU Mo-99 Production	Brandy Gartman, Nicholas Uhnak, Andrew Ritzmann	PNNL / USA
			7. Savannah River National Laboratory Technical Support for Non-HEU Mo-99 Production	James Klein, Tracy Rudisill, Jake Amoroso	SRNL / USA
			8. Y-12 National Security Complex Technical Support for Non-HEU Mo-99 Production	Lloyd Jollay, Denise Harmening	Y-12 / USA
			9. Separation and Purification of Tc-99m from Simulated Molybdenum Target	Przemysław Koźmiński	INCT / Poland

#	Session Title	Time	Topic	Presenter	Organization/ Country
5	Technology Development Updates I Session Chair - Bhavini Singh	4:10 pm	1. Development of Mesoporous Alumina Using Pluronic-123 as a Soft Template for Non-Fission Mo-99/Tc-99m Generator Column	Indra Saptiama	BRIN / Indonesia
		4:30 pm	2. A Porous Reusable UO2 Target to Increase the Sustainability of Mo-99 Manufacturing	Robert Raposio	ANSTO / Australia
		4:50 pm	3. Studies on Production of Mo-99 Through Mo-100(γ,n)Mo-99 Nuclear Reaction In Simulated Processing Conditions	Izabela Cieszykowska	POLATOM / Poland
5:10 pm Adjourn					
Friday, October 7					
Meeting Room: IAEA C-Building (Fourth Floor) Board Room C					
6	Regional and Future International Production Session Chair - Nil Neda Bedro	9:00 am	1. IAEA Activities in Support of Production of Mo-99 and Mo-99/Tc-99m Generators	Amirreza Jalilian	IAEA
		9:25 am	2. Korean Mo-99 Project and New Research Reactor Progress	Seung-Kon Lee	KAERI / Republic of Korea
		9:50 am	3. Current Status of Mo-99 Production and Future Prospects in Argentina	Natalia Stankevicius	CNEA / Argentina
10:20 am Self-Hosted Refreshment Break					
7	Mo-99 Supply Chain Perspectives Session Chair - Seung-Kon Lee	10:50 am	1. Coordinated International Efforts for a Reliable Supply of Medical Radioisotopes	Ira Goldman	Lantheus / USA
		11:10 am	2. Cardinal Health Nuclear & Precision Health Solutions: Perspectives on the Reliable Supply of Molybdenum-99	David Pellicciarini	Cardinal Health / USA
		11:30 am	3. Development of Supply Chain Performance Measurement System Based on a Multicriteria Decision Aid Prométhée-II for Mo-99 Integrated Supply Chain	Haingo Rabarijaona	Université Libre de Bruxelles / Belgium
		11:50 pm	4. My 15 Year Perspective on the Mo-99 Shortage, What Did We Learn?	Orhan Suleiman	Consultant / USA
12:10 pm Lunch Break					
8	Regulating and Enabling Mo-99 Production Session Chair - Hertzog Bisset	1:40 pm	1. U.S. Food and Drug Administration: Regulatory Considerations in the US on Mo-99 Produced by LEU and Novel Technologies	Danae Christodoulou	FDA / USA
		2:00 pm	2. ESA Activities to Support the Secure Supply of Medical Radioisotopes in the EU	Remigiusz Baranczyk	Euratom Supply Agency / Luxembourg
		2:20 pm	3. Licensing and Oversight of Mo-99 Programs at the U.S. Nuclear Regulatory Commission	Michael Balazik	NRC / USA
		2:40 pm	4. Source Term Analysis of Xenon (STAX) Project, A Collaboration Between Medical Isotope Production and Nuclear Explosion Monitoring Communities	Judah Friese	PNNL / USA
3:00 pm Self Hosted Refreshment Break					
9	Technology Development Updates II Session Chair - Kyle Sallee	3:30 pm	1. General Precautions Related to Preparation and Use of Mo-99/Tc-99m Generators Based On Alumina Chromatographic Columns	M. Mostafa	EAEA / Egypt
		3:50 pm	2. Development of a Plasma-Aided Fluorination Process for Mo-99 Separation	Tobias Chemnitz	TUM / Germany
		4:10 pm	3. Summary and Outcomes of IAEA CRP on “New Ways of Producing Mo-99/Tc-99m and Tc-99m Generators”	Aruna Korde	IAEA
4:30 pm Summary and Meeting Closure					
5:00 pm Adjourn					

SESSION ABSTRACTS

SESSION 1 Opening Plenary Session: Supporting a Reliable, Non-HEU Mo-99 Supply

Session Chair: Christopher Landers

1.1 IAEA Deputy Director General Opening Remarks

Mikhail Chudakov

*Deputy Director General and Head of the Department of Nuclear Energy
International Atomic Energy Agency*

1.2 U.S. Mission Opening Remarks

Ambassador Laura S.H. Holgate

*U.S. Ambassador to the Vienna Office of the United Nations and to the International Atomic
Energy Agency*

1.3 DOE/NNSA Opening Remarks

Jeff Chamberlin

*Assistant Deputy Administrator for Material Management and Minimization
U.S. Department of Energy's National Nuclear Security Administration*

1.4 IAEA Staff Opening Remarks

John Dewes

*Nuclear Engineer, Research Reactor Section
International Atomic Energy Agency*

SESSION 2 Perspectives from Current Global Mo-99 Producers

Session Chair: Ira Goldman

2.1 NNSA Office of Conversion: Ending HEU in Mo-99 Production

Brett Cox

*U.S. Department of Energy's National Nuclear Security Administration
1000 Independence Ave., Washington DC 20585 – USA*

2.2 Reflections on Five Years of LEU-Based Production of Medical Radionuclides

Roy Brown

Curium

111 Westport St., Suite 800, St. Louis, MO 63043 – USA

Curium is the largest producer and consumer of Mo-99. The conversion from HEU to LEU for Curium started in 2010 and entailed several years of planning, development implementation and systems validation to convert to a LEU-based process for production of medical radionuclides. That journey has been challenging but rewarding knowing that HEU has been removed from circulation and the world is safer as a result. The U.S. Department of Energy has been a valued partner during that conversion for their financial and technical support. We continue to monitor the global supply of HA LEU upon which we are now reliant. A reliable and sustainable supply of HA LEU is critical for the field of nuclear medicine and the patients we serve with diagnostic and therapeutic radiopharmaceuticals. New therapeutic medical radionuclides currently in use and those being developed rely on LEU-based fuel in research reactors throughout the world. This makes the supply of HA LEU even more critical.

2.3 All LEU Mo-99 Production Experience

*A Ntlokwana, PA Louw, G Ball
NTP Radioisotopes SOC Ltd
PO Box 582, Pretoria, 0001 - South Africa.*

NTP Radioisotopes SOC Ltd (NTP) manufactures and supplies significant quantities of Mo-99 to the global nuclear medicine industry from its Mo-99 production facilities located at Pelindaba. The production process is based on LEU targets irradiated in the LEU fueled SAFARI-1 research reactor which is also located at Pelindaba. In support of the Global Threat Reduction Initiative of the U.S. Department of Energy to completely eliminate the use of HEU in Mo-99 manufacturing processes, NTP invested significantly in the conversion of the SAFARI-1 fuel and the uranium targets for the Mo-99 production from HEU to LEU. Not only was investment required in the irradiation and processing of targets but this also included investing in the downstream irradiated uranium handling and storage facilities. 'All LEU' (LEU reactor fuel and targets) based Mo-99 is currently routinely manufactured at significantly increased operational costs compared to HEU based processes without proper compensation from Industry. Conversion of Mo-99 manufacturing from HEU to LEU targets require significant investments in research and development, infrastructural changes, nuclear licensing (at the reactor and processing facility) and product registration. NTP successfully completed these and built substantial experience over the past more than 10 years to ensure long-term sustainable production of all LEU based Mo-99. NTP also extracts I-131 from its fission Mo-99 process with the implication that NTP also supplies 'all LEU I-131'.

The supply of Mo-99 and I-131 over the past few years was in turmoil because of the Covid pandemic that played havoc with market demand and logistics. This was complicated even more by supply interruptions emanating from a combination of extended scheduled and unscheduled shutdowns of some reactors and Mo-99 and I-131 processing facilities.

NTP's presentation will share NTP's experience in LEU Mo-99 and I-131 production and specifically also address challenges and successes since the inception of Covid-19.

2.4 Achievements of the IRE LEU Conversion Program

*Valery Host
National Institute for Radioelements (IRE)
Av. de l'Esperance, Fleurus – Belgium*

IRE is actively participating in the reduction of proliferation risks through its commitment to convert its radioisotope production lines to the use of LEU targets. Important milestones have been achieved so far, confirming the continuous progress of the project.

All production processes, including Mo-99, I-131 and Xe-133 are now fully validated allowing the regular supply of the market with LEU based isotopes. The IRE customer validations are progressing well but still drive the progressive phase out of HEU process which, to avoid any shortage in the supply of I-131, has been extended to Q1 2023.

The presentation provides an overview of the project and the remaining challenges to overcome to achieve the complete HEU phase out.

SESSION 3 North American Mo-99 Production Projects

Session Chair: Max Postman

3.1 Update on Domestic Production of Mo-99

*James T. Harvey
NorthStar Medical Technologies
LLC, 1800 Gateway Blvd, Beloit, WI 53511 – USA*

NorthStar has multiple efforts towards establishing a reliable domestic production of Mo-99. One effort is reactor based utilizing the neutron capture process at the Missouri University Research Reactor (MURR) reactor which gained FDA approval in February 2018 and has been in production since November 2018. The second effort is an electron accelerator-based process utilizing the photon capture process at NorthStar's Beloit site. In either case a new type of generating system that is capable of accepting a low specific activity solution of Mo-99 and yielding a USP compliant, high activity concentration Tc-99m product was developed and approved. NorthStar's presentation will describe current status of the domestic Mo99 production, inspection and approval of NorthStar's production facilities by the U.S. FDA and the U.S. FDA Approval of RadioGenix® Tc-99m generating.

3.2 New Infrastructure for Neutron Based Medical Isotope Production

Greg Piefer
SHINE Technologies, LLC
3400 Innovation Ct., Janesville WI 53546 – USA

SHINE Technologies is a next-generation nuclear technology company with a mission to deploy cost-effective fusion-based solutions to solve some of humanity's biggest problems. Our long-term strategy involves incremental improvements to state-of-the-art fusion technology aimed at producing real commercial value along the way.

Today, we're focused on fusion-driven systems to replace aging reactor infrastructure for medical isotope production. These systems are expected to be more cost-effective, produce less radioactivity, and be safer than their reactor-based counterparts. We're now completing construction on what we believe will be the largest medical isotope production factory in the world, located in Janesville, WI, and have plans to replicate that facility in Veendam, the Netherlands. Each of these factories will be able to produce the suite of fission-based isotopes, and neutron-capture isotopes that involve a transmutation. Our factories include integrated irradiation and processing infrastructure that will deliver finished isotopes comparable to their reactor-produced counterparts.

3.3 Mo-99 Production – Neutron Capture-Based Production via Power Reactor and Potential Market Penetration

Andrew Lukomski, Jamie Leebody
Laurentis Energy Partners
889 Brock Road, L1W 3J2, Pickering – Canada

Michael Flagg
BWXT Medical
447 March Road, K2K 1X8, Kanata – Canada

Historically, the production of molybdenum-99 (Mo-99) via neutron capture has been limited, stemming from lower reaction efficiencies and extraction capacities based on low specific activity. A breakthrough in technetium generator technology, developed by BWX Technologies (BWXT) in the United States, has regained attention as a viable method for high-volume uranium-based Mo-99 production. Through a partnership with Laurentis Energy Partners of Canada, a commercial CANDU (Canadian Atomic Natural Deuterium Uranium) nuclear reactor near Toronto, Canada, will generate Mo-99 via neutron capture with subsequent processing at a local BWXT facility – both technologies being a first of a kind in the industry. Given the scale of power reactors, additional operating and safety considerations beyond those incorporated in research reactors will be required for the production and handling of Mo-99. This paper discusses non-proprietary aspects of neutron capture-based Mo-99 production through a commercial reactor in support of potential market expansion in other CANDU-type heavy water reactors or other future reactor designs.

3.4 Niowave's US Production of Mo-99 and other Fission Products

William A. Peters, Terry Grimm, Robert Wahlen, Nathan Johnson, Chase Boulware
Niowave Inc
Lansing, Michigan, 48906 USA

Niowave manufactures radioisotopes to cure cancer and save lives. In 2019, and again in 2021, Niowave became a cooperative agreement partner with the U.S. NNSA, tasked with creating a reliable and sustainable US domestic supply of molybdenum-99 (Mo-99) without the use of highly enriched uranium and a nuclear reactor.

Niowave is operating a closed-loop uranium cycle to produce Mo-99 and other fission products from uranium without the use of a nuclear reactor. Niowave manufactures and utilizes its own superconducting electron linear accelerators to irradiate and induce fission in a subcritical assembly of natural uranium and low-enriched uranium. After irradiation, and an initial cooling period, volatile fission products are removed cryogenically followed by chemically processing the uranium targets. Uranium, plutonium, and neptunium is separated from the fission products by a modified UREX process. The Mo-99 and other fission products are then purified through a series of liquid-liquid extraction or resin-based separation processes. The uranium and transuranic elements are then recovered, loaded in rods, and then inserted back into the subcritical assembly; closing the uranium cycle.

This presentation will go through some of Niowave's achievements, highlighting work done jointly with NNSA laboratory partners and our path toward commercial-scale Mo-99 production.

SESSION 4 Poster Session

Session Chair: Caryn Warsaw

4.1 The Decay Vendor: A Stochastic Model for Medical Radioisotope Supply Chains

Tiffany-Thao Nguyen, Joachim Arts
University of Luxembourg
6 Rue Richard Coudenhove-Kalergi, 1359 Luxembourg City – Luxembourg

Stefan Holmström, Jared Wight
SCK CEN
Belgian Nuclear Research Centre – Boeretang 200, 2400 Mol – Belgium

This poster presents a basic mathematical model of a supply chain with radioactive decay. The model is based on the classical newsvendor problem used in supply chain to determine optimal inventory of a perishable product. The decay vendor problem we present contains a combination of fixed events, stochastic process times, and a radioactively decaying product. We explore different methods of modelling and optimization.

The decay vendor model is an initial step in a PhD project to create a discrete-event simulation tool of the entire Mo-99/Tc-99m supply chain. This tool can help anticipate how disruptions affect different parts of the supply chain. Such results can be used to create contingency plans to evaluate the effectiveness of such plans in the same simulation model. This iterative process can improve the supply chain security, speed, and alignment.

4.2 NEXT Lab: Mission, Achievements, and Mo-99 Interest

Diego F. Zometa Panigua
NEXT Lab, Abilene Christian University
Campus Court 1600, 79699 Abilene Texas – USA

The NEXT Lab seeks to provide global answers to the world's needs of clean energy, clean water, and access to medical radioisotopes by building a fluoride molten salt reactor. This reactor is designed to be fueled with high-assay low enriched uranium (HALEU) dissolved

in ${}^7\text{LiF-BeF}_2$ and operate at a maximum power of 1 MW_{th}. The construction license application for this reactor was recently submitted to the U.S. Nuclear Regulatory Commission (NRC), and construction on a facility designed to contain the reactor is underway. One of the isotopes of interest, molybdenum-99 (Mo-99), is expected to be one of the products of the reactor. Calculations indicate that at full power this reactor could annually generate enough Mo-99 to exceed the current U.S. annual demand. The focus of recent research has been on the extraction of Mo-99 from molten salt and subsequent purification of Mo-99 from among known corrosion products and other fission fragments.

4.3 Argonne National Laboratory Technical Support for Non-HEU Mo-99 Production

4.3.1 Process Design & Development for Electron Accelerator-Driven Mo-99 Production from U₃O₈ Targets.

M. Alex Brown, Anna Servis, Yana Karslyan, Khyra Neal, Jim Byrnes, Sergey Chemerisov, Peter Tkac

Argonne National Laboratory

9700 S. Cass Ave, Lemont, IL 60439 – USA

Super conducting electron LINACS (linear accelerators) have the capability to induce neutron fluxes and photo-fission sufficient enough to produce medical isotopes from uranium targets and exhibit a number of advantages over conventional research reactor sources. This technology has been adopted by NNSA cooperative agreement partners to meet the U.S. Mo-99 demand. To facilitate this effort, Argonne has developed new chemical processes that are compatible with large U₃O₈ targets and subsequent purification of Mo-99 from other fission and activation products. These processes leverage new solvent extraction and anion exchange platforms. The fundamental chemistry, scale-up, and collaborative efforts are discussed.

4.3.2 Removal of Tc-99, Zr-95, and Nb-95 from Solutions Obtained After Dissolution of Irradiated Mo Targets

D. Bettinardi, A. Servis, P. Tkac

Argonne National Laboratory

9700 S. Cass Ave, Lemont, IL 60439 – USA

Removal of ground state Tc-99 that accumulates during Mo-99 production could allow the first elution of a Tc-99m generator to be used instead of discarded. Here, we report the experimental results on removal of Tc-99 (10 µg/mL) from low-specific-activity Mo-99 solutions prior to loading onto a Tc-99m generator. Removal was accomplished through the reduction and simultaneous immobilization Tc(VII) with Fe(II), producing an insoluble, Tc-incorporated Fe(II)-Fe(III) solid that was filtered off. Large-scale testing showed that >95% Tc can be removed without affecting Mo-99 yields. Two other important side reaction product impurities in irradiated, enriched Mo-98 and Mo-100 targets, Zr-95 and Nb-95, were also removed (>99%) in this process. The effects of Fe, Tc, and Mo concentrations, Fe(II)/Fe(III) ratio, pH, temperature, and hydrogen peroxide addition were tested.

4.3.3 Design of Universal Neutron Irradiation Target Station and Execution of Experiments on Long Duration Irradiation of Uranyl Sulfate Solution

S. Chemerisov, P. Tkac, M. Kalensky, J. Bailey, P. Strons, K.J. Quigley, R. Gromov, A. Patapenka, A. Servis, K.A. Wesolowski, C.D. Jonah, K. Alford, D. Mullins, J. Hlavenka, R. Kmak

Argonne National Laboratory

9700 S. Cass Ave, Lemont, IL 60439 – USA

Argonne is assisting SHINE Medical Technologies in developing commercial production of Mo-99 medical isotope without use of HEU. To conduct experimental studies of uranyl

sulfate solution behavior in high radiation field Argonne has developed a neutron generating target system that allows irradiation of 50 ml of solution at the fission powers and temperature similar to SHINE production unit. Universal neutron irradiator incorporates high-Z converter, neutron reflector, solution capsule, temperature control systems, and catalytic hydrogen/oxygen recombiner. Interaction of high energy electron beam with high-Z converter generates high flux of Bremsstrahlung photons inducing photonuclear reaction in the solution target and surrounding beryllium reflector. Design of the dry well allows placement of different samples inside high neutron flux region for future studies. In this presentation we will discuss experimental setup design and results of initial experiments.

4.3.4 Design of the Test Bench for of Uranium Foils Dissolution

S. Chemerisov, P. Tkac, J. Bailey, P. Strons, R. Kmak
Argonne National Laboratory
9700 S. Cass Ave, Lemont, IL 60439 – USA

Argonne is assisting Eden in developing technology for commercial production of Mo-99 medical isotope without use of HEU. To assist in optimization of dissolution process Argonne has designed and built a dissolver apparatus that can handle dissolution of up to 750 g of uranium foils at wide range of temperatures and pressures. The aim of the dissolution demonstrations is to achieve efficient dissolution at sub-atmospheric pressures. To control gas pressure build-up, the dissolver is equipped with condenser coils to reflux water and to capture NO_x gasses. It also incorporates pump for NO_x gas recirculation and oxygen addition system for NO_x conversion, which will contribute to decreased pressure, lower amount of acid used for dissolution, and decrease the dissolution time. Dissolver test bench was assembled, and operations of all components were verified. In this presentation we will discuss experimental setup design and results of initial tests.

4.3.5 Argonne Support for Accelerator-Based Production of Mo-99

S. Chemerisov, P. Tkac, P. Strons, A. Patapenka, J. Bailey, and Guosheng Ye
Argonne National Laboratory
9700 S. Cass Ave, Lemont, IL 60439 – USA

NorthStar Medical Isotopes is planning to produce Mo-99 by Mo-100(γ, n)Mo-99 reaction using high power electron accelerators. Significantly smaller amount of co-produced radioisotopes and their relatively short half-life in photonuclear production of Mo-99 is making accelerator-based production an attractive alternative to the traditional way of producing Mo-99 through uranium fission. On the other hand, low cross section for photonuclear production creates significant challenges for target and cooling system design. Argonne is providing support to NorthStar in Monte Carlo, CFD and structural modeling of the production target system. Also, Argonne has designed a scaled down target for experimental verification of molybdenum target behavior during electron beam bombardment at Argonne's electron accelerator facility. In this presentation we will discuss results of computer simulations, experimental setup design and results of initial experiments.

4.3.6 Argonne Support for Domestic Production of Mo-99

P. Tkac, S.D. Chemerisov, M. Kalensky, J.F. Krebs, M.A. Brown, T. Brossard, D. McLain, J. Bailey, P. Strons, K.J. Quigley, J.P. Byrnes, R. Gromov, A. Patapenka, D.J. Bettinardi, A. Servis, Y. Karslyan, K.A. Neal, K.A. Wesolowski, C.D. Jonah, K. Alford, D. Mullins, J. Hlavenka, R. Kmak
Argonne National Laboratory
9700 S. Cass Ave, Lemont, IL 60439 – USA

Argonne is assisting several potential U.S. producers of Mo-99 in developing technologies for commercial production of this important medical isotope without HEU. This includes Monte Carlo, CFD and structural modeling, in-beam target irradiations, hot cell processing, development, and optimization of purification flowsheets, recycle of target material and scale-up processes. Among others, several key successes include completion of irradiation campaign of 20 L low-enriched uranyl sulfate solution, scaled up conversion of U metal to uranyl sulfate, accelerator production of 54 Ci Mo-99, development and testing of solvent extraction-based separation flowsheet, and design and testing of a large-scale dissolver for up to 750 g of U. This presentation will highlight the important work that Argonne is doing to support the NNSA's domestic Mo-99 program.

4.3.7 Development of Low Specific Activity Mo-99/Tc-99m generator

P. Tkac, D.J. Bettinardi, M.A. Brown, K. Neal
Argonne National Laboratory
9700 S. Cass Ave, Lemont, IL 60439 – USA

There are several alternatives to fission-based production of Mo-99/Tc-99m. While neutron capture via $\text{Mo-98}(n, \gamma)\text{Mo-99}$ reaction still requires a nuclear reactor as a neutron source, alternative production methods using $\text{Mo-100}(\gamma, n)\text{Mo-99}$ or direct production of Tc-99m via $\text{Mo-100}(p, 2n)\text{Tc-99m}$ can be achieved using commercially available accelerators. A generator system that can handle high chemical concentration of Mo is needed to separate the trace amount of Tc-99m from low-specific-activity Mo-99. Here we discuss a generator concept where bulk Mo is separated from Tc by precipitation of Mo in ethanol, while ethanol-soluble pertechnetate is recovered by filtration. The precipitated molybdate salt is then redissolved in water or saline solution for another milking. This approach allows handling gram-quantities of Mo, separates >99.99% Mo by precipitation, and yields ~90% Tc recovery. Mo remaining in ethanol is captured on alumina column. Advantages and disadvantages of this approach will be discussed.

4.3.8 Impact of Irradiation and Decay Time on Chemical Speciation in Uranyl Sulfate Solution

Anna G. Servis, Michael Kalensky, Sergey D. Chemerisov, Roman G. Gromov, Charles D. Jonah, Andrei S. Patapenka, Josh Hlavenka, David Mullins, Kurt Alford, Kenneth A. Wesolowski, and Peter Tkac
Argonne National Laboratory
9700 S. Cass Ave, Lemont, IL 60439 – USA

SHINE Medical Technologies plans to produce Mo-99 using an accelerator-driven neutron generator to fission U-235 in a subcritical uranyl sulfate solution. In this work, five irradiations of a 50 mL pH 1, uranyl sulfate target were completed to explore the impact of irradiation and decay time on uranium precipitation and the formation of volatile iodine species. Subsamples of the fission solution and images inside the target capsule were collected after each irradiation of increasing length. Precipitation was not observed in the solution after any of the irradiations, both within the first 48 hours and up to 26 days later. Volatile molecular iodine was found to make up as much as 21% of the total iodine species in solution after 131 hours (5.5 days) of decay time, having reached equilibrium with nonvolatile iodide and iodate species. Small amount of I-131 were observed in gas samples taken from the headspace of the capsule, indicating that some iodine is lost from the solution to the vapor phase.

4.4 Los Alamos National Laboratory Technical Support for Non-HEU Mo-99 Production

4.4.1 Flow and Heat Transfer Analysis of the NorthStar Mo-99 Production Target

B. Singh, E. R. Olivas, A. J. Wass and K. A. Woloshun
Los Alamos National Laboratory

P.O Box 1663, Los Alamos, NM 87545 – USA

The NorthStar target consists of an Inconel window that allows an electron beam to penetrate and irradiate a stack of Mo-100 discs, cooled using pressurized helium gas. Before beam on target, the design is tested at LANL using a variety of experiments and accompanying computational fluid dynamics and heat transfer simulations. In the experiments, induction heating is used to simulate volumetric heating on the window, as well as a single disc and is accompanied by disc displacement and window temperature measurements. High speed imaging and laser-based diagnostics are also used to investigate the system, including flow induced vibrations and the path of the helium gas around the target housing. Computational models of the full target provide a complete picture of the effect of beam heating and helium flow through the target and the viability of the current design. Results from the experiments and modeling efforts are presented.

4.4.2 Preliminary Design and Analysis and Testing of the Niowave 200 KW Lead-Bismuth Electron-Neutron Converter

*E. Olivas, C. Miera, T. Roybal, K. Woloshun
Los Alamos National Laboratory
Bikini Atoll Road, 87545 – USA*

Niowave is developing a Mo-99 production method that is centered on an accelerator driven sub-critical reactor technique. The initiating neutron flux is created by passing an electron beam through a liquid layer of lead-bismuth eutectic (LBE). This converter, a windowless or waterfall concept, is designed and analyzed computationally by LANL. The converter is mounted onto and partially within an array of water-cooled uranium rods where the Mo-99 is produced. The design and computational fluid dynamic results are the subject of this poster.

4.4.3 Predicting Solution Reactor Operational Behavior in Support for Mo-99 Production for SHINE Technologies

*A. J. Wass and C. E. Buechler
Los Alamos National Laboratory
P.O. Box 1663, Los Alamos, NM 87545 - USA*

Los Alamos National Laboratory (LANL) has been supporting SHINE Technologies in scientific research towards the production of Mo-99 without the use of highly enriched uranium for over a decade. LANL has primarily performed studies in areas involving fluid and thermal dynamics and neutronics. This includes computational fluid dynamics (CFD) studies of multiphase flow in laminar and turbulent regimes and natural convective heat transfer. Specifically, CFD was used to simulate the natural convection and bubble induced mixing of the uranyl-nitrate reactor, SUPO. SUPO, or “Super-Power” was operated from 1951 to 1974 at what is currently called LANL, and has played an important role in validating our CFD capabilities. Using historical data from SUPO and experimental data from Argonne National Laboratory (ANL), we are able to better understand the accuracy of our models and simulations. We will discuss these studies in detail.

4.4.4 LANL Mo-99 Production Support

*Keith Woloshun, Eric Olivas, Alex Wass and Bhavini Singh
Los Alamos National Laboratory
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Los Alamos has been providing engineering, design and experimental support to NorthStar Medical Radioisotopes, SHINE Technologies and Niowave as they develop their systems for production of the medical isotope Mo-99. Work with NorthStar started in 2010. In their system a stack of Mo-100 thin disks are irradiated with 40 MeV electrons to produce the Mo-99. These disks are cooled by a high velocity, elevated pressure flow of helium.

Niowave is using a falling film of liquid metal, the lead-bismuth eutectic (LBE). Also, using a 40 MeV electron beam, on striking the LBE a cascade of neutrons is created that produces Mo-99 from uranium rods. For over a decade, LANL has performed studies in areas involving fluid and thermal dynamics and neutronics for SHINE Technologies. This includes computational fluid dynamics (CFD) studies of multiphase flow in laminar and turbulent regimes and natural convective heat transfer relating to sub-critical assemblies. This poster is intended as an overview of LANL activity in support of these programs.

4.5 Oak Ridge National Laboratory Technical Support for Non-HEU Mo-99 Production

4.5.1 Oak Ridge National Laboratory Mo-99 Program

J. Navarro and J. Nash

Oak Ridge National Laboratory

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Since 2010 ORNL has participated in the NNSA Mo-99 program. As part of that program, researchers at ORNL have collaborated with a variety of companies in the development of R&D solutions to overcome fabrication, production, licensing, and potential operational challenges. Most recently, ORNL has been focused on supporting the efforts of five companies: NorthStar, Shine, BWXT, Eden and Niowave. This support has included target material production and material processing method development (NorthStar), material performance evaluations (SHINE, Eden), material capsule and prototypic target design (BWXT, Eden), HFIR material and target irradiation testing (SHINE, Eden, BWXT), as well as core neutronics, thermal, and shielding design support (Niowave). These efforts will continue in the upcoming year as ORNL provides support to companies as they progress through the final design phase, licensing process, and transition into operation.

4.5.2 Oak Ridge National Laboratory Design and Shielding Support for Accelerator Driven Sub-Critical Assembly use for Mo-99 Production

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Oak Ridge National Laboratory is actively collaborating with industrial partners through the National Nuclear Security Administration's program to establish a reliable supply of Mo-99 without using highly enriched uranium. One area of focus has been supporting the use of accelerator driven sub-critical reactor (ADSR) facilities for Mo-99 production, specifically supporting design, optimization, and shielding strategy development. The coupled, multi-physics nature of ADSRs, make them challenging environments to analyze. Therefore, ORNL researchers have focused on adapting and developing methodologies to better understand, characterize, and optimize these systems. Methodologies include traditional sensitivity analyses, machine learning techniques, and development of surrogate models. ORNL has also demonstrated that existing capabilities (e.g., MCNP methods, scripting, SCALE) can be used for complex shielding evaluations associated with ADSRs. However, the research team is actively partnering with SCALE to incorporate photonuclear capabilities and provide a comprehensive modeling and simulation suite that can be utilized for ADSR system evaluations.

4.5.3 Mo-99 Target Design and Irradiation Testing in the High Flux Isotope Reactor

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The U.S. Department of Energy's National Nuclear Security Administration has an objective to establish a reliable supply of Mo-99 without using highly enriched uranium.

Collaborative research and development between Oak Ridge National Laboratory and industrial partners has focused on supporting that objective using the High Flux Isotope Reactor. This reactor offers the ability to qualify fueled targets that will be used in future production efforts by these partners. Numerical methods for the design of targets for irradiation testing include neutronics analyses using Monte-Carlo N-Particle methods, finite volume simulations of computational fluid dynamics and systems-level thermal-hydraulics, along with finite element computations for fuel performance and thermal stress. Design considerations for normal and abnormal operations must be made for the target, as well as the safety-related coupled behavior between the target experiments and the HFIR core. Irradiation campaigns are underway to test a variety of target fuel forms and validate numerical solutions.

4.6 Pacific Northwest National Laboratory Technical Support for Non-HEU Mo-99 Production

4.6.1 Spectroscopic Evaluation of Iodine Radiolysis with Exposure to a Co-60 Source

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Understanding iodine speciation transformation in solution conditions and radiolysis effects on speciation has been an on-going endeavor, where more data collection is required to help improve and validate thermodynamic equilibrium models and kinetic models. Characterization of iodine behavior was studied in a variety of conditions, including the use of PNNL's Radiological Exposures and Metrology (REM) Laboratory to study dose effect when exposed to a Co-60 source. Analysis of the samples encompassed using a variety of spectroscopic techniques including I-127 NMR spectroscopy, Raman spectroscopy, Fourier Transform Infra-red spectroscopy (FTIR), and ultraviolet-visible (UV-Vis) spectroscopy to measure iodine species such as I_2 , IO_3^- , IO_4^- , and I_x^- (where $x = 3, 5, 7$, etc.). In addition to spectroscopic data, redox measurements were also collected to characterize changes to the solution conditions. Results collected from this study provide an understanding of detection limits and iodine behavior across a wide range of conditions and concentrations, which ultimately will provide data to validate the models.

4.6.2 PNNL Support for NNSA's Mo-99 Conversion Program

Nicolas Uhnak, James Hayes, James Bowen, Andrew Ritzmann, Russell Burnett, Vincent Woods, Brad Fritz, Leah Arrigo, Paul Humble, Brandy Gartman, Dallas Reilly

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Molybdenum-99 (Mo-99) production in the United States is being encouraged with the aid of the National Nuclear Security Administration's (NNSA) Office of Conversion (NA-231). Pacific Northwest National Laboratory is aiding in these efforts through two primary activities, the first, radioxenon emissions abatement, and the second, improvement in the understanding of iodine chemistry to aid in the eventual capture of the radioiodine. These activities include significant efforts in modeling carbon delay beds, modeling iodine chemistry kinetically and thermodynamically to aid capture techniques, characterization of iodine speciation under different radiochemical or radiolytic conditions, development of cooled abatement traps, as well as efforts to integrate the radioxenon and radioiodine capture efforts to minimize emissions.

4.6.3 Modeling Activated Carbon Traps for Radioxenon Abatement in Medical Isotope Production Facilities

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The United States National Nuclear Security Administration has established the goal of accelerating the development of a reliable commercial domestic supply of Mo-99 using low enriched uranium or alternate processes that don't require highly enriched uranium. Regulatory approval for Mo-99 production requires proper abatement of radioxenon emissions. Effluent gas streams are typically passed through delay beds containing activated carbon (e.g., NUCON® GXK-6X12) that adsorb the xenon and allow the radioactive isotopes to decay below required limits. This work presents a numerical model for quantifying the performance of delay beds. Experimental xenon adsorption isotherms for NUCON® GXK-6X12 are also presented. The model couples gas transport through the bed, gas adsorption to the carbon, and the radioactive decay heating. Results generated by this model illuminate how bed size, flow rate, and temperature influence the radioxenon abatement performance of the delay beds.

4.7 Savannah River National Laboratory Technical Support for Non-HEU Mo-99 Production

4.7.1 SRNL Tritium Development Activities for Accelerator Mo-99 Production

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SRNL has supported accelerator production of Mo-99 since 2012. Use of deuterium accelerators using a tritium target require additional study and development for gas handling, processing, storage, confinement, and waste disposal. A brief description of some studies performed by SRNL to support Mo-99 production will be presented.

4.7.2 Nuclear Material Processing Development Activities at the Savannah River National Laboratory to Support the U.S. Production of Mo-99

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The Savannah River National Laboratory is supported by the National Nuclear Security Administration to provide R&D assistance to potential new U.S. Mo-99 producers. The assistance includes the development of flowsheets for the purification of uranium from dissolved targets following Mo-99 recovery and the removal of high specific activity fission products from waste streams to lower the classification (e.g., Class C to Class A or B) of the waste form. A modified PUREX process was demonstrated for nominally 90% uranium recovery allowing the purge of a small amount of uranium from the inventory each cycle to minimize the production of plutonium during subsequent target irradiations. In small column tests using ammonium molybdophosphate and crystalline silicotitanate (R9120-B) with a simulated acidic sulfate waste solution containing uranium, plutonium, neptunium and non-rad fission product, both ion exchange materials were highly specific for cesium. Neither material removed significant strontium or uranium.

4.7.3 Management and categorization of wastes resulting from Mo-99 production

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Appropriate waste management strategies are critical to the production of Mo-99 using low enriched uranium (LEU). There are various Mo-99 production processes for which unique methods and strategies for treatment and disposal of the waste streams is needed. Product specifications, acceptance criteria, facility design, and process operations must all

be considered as part of the overall waste management strategy. Recently, the Savannah River National Laboratory (SRNL) has been providing technical assistance and lessons learned to potential producers in the United States regarding waste acceptance, qualification, and disposal requirements. Relevant best practices and discussion regarding waste management and disposal options will be presented.

4.8 Y-12 National Security Complex Technical Support for Non-HEU Mo-99 Production

4.8.1 Y-12 FY 22 Contribution to Domestic Mo-99

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As directed by the American Medical Isotopes Production Act of 2012, NNSA is working with commercial partners to accelerate the establishment of a reliable supply of Mo-99 in the United States, produced without highly enriched uranium (HEU). Y-12 is working with Niowave in FY 2022 to convert HALEU metal (9.75% U-235) into U_3O_8 . This oxide is pressed into pellets or rods to be irradiated in the Uranium Target Assembly. Y-12 is also providing performance demonstration testing on loading driver rods with DU oxide. Y-12 is also working with Eden Radioisotopes to develop annular targets that will be irradiated for the production of Mo-99. Y-12 will cast, roll, shape, and coat full size DU foils for target insertion, hydroforming, and end sealing. As part of this effort a plating method for the monolithic target meat is being developed.

4.8.2 Y-12 Supply of High Assay Low Enriched Uranium and Overview of the Uranium Lease and Take-Back Program

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The Y-12 National Security Complex (Y-12) downblends highly enriched uranium (HEU) to produce high assay low enriched uranium (HALEU). The HALEU is cast, sampled, sized, and packed to the Y-12 Standard Specification Low Enriched Uranium Metal Supply to Research and Test Reactors.

In 2012, Congress passed the American Medical Isotopes Production Act (AMIPA), which directed the National Nuclear Security Administration (NNSA) to establish a technology-neutral program to support the establishment of domestic supplies of Mo-99 without the use of HEU. Per AMIPA, the Uranium Lease and Take-Back Program (ULTB) is managed jointly by the NNSA and the Department of Energy's Office of Environmental Management. Under this program, NNSA makes HALEU available through lease contracts for the production of Mo-99 for medical uses. Y-12 assists in developing and executing HALEU supply lease contracts, developing and coordinating HALEU production and deliveries, and coordinating and tracking HALEU requirements from potential ULTB customers.

4.9 Separation and Purification of Tc-99m from Simulated Molybdenum Target

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A semi-automated purification module for the cyclic separation of Tc-99m was designed for production of $[Tc-99m]TcO_4^-$ from γ irradiated Mo-100 target. The separation process was carried out by using a 3-column purification system and the final product, $[Tc-99m]TcO_4^-$, was obtained in a total volume of 7 mL. To confirm proper separation achieved for Tc-99m, a radio-labeling procedure using DTPA chelator was performed. The

radiochemical purity was higher than 95%, which meets the strict radiopharmaceutical requirements. The yielded Tc-99m can be separated with high efficiency from Mo in a quick and repeated way. Loss of Tc-99m radioactivity during such a three-column separation process was not larger than 10%.

SESSION 5 Technology Development Updates I

Session Chair: Bhavini Singh

5.1 Development of Mesoporous Alumina Using Pluronic-123 as a Soft Template for Non-Fission Mo-99/Tc-99m Generator Column

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Mesoporous alumina was prepared using a pluronic-123 (P-123) template for non-fission Mo-99 adsorbent through a soft-templated method. The effect of calcination temperature on the Mo adsorption capacity and the separation of Tc-99m from the Mo-99 in the generator column was experimentally investigated. The characterization of the mesoporous alumina calcined at 700 °C (MA-700), 800 °C (MA-800), and 900 °C (MA-900), by multi-step calcination was performed by using XRD and N₂ adsorption/desorption techniques. The crystalline structure of the mesoporous alumina was transformed into amorphous alumina at 700 °C and gamma alumina at 800 to 1000 °C. The BET surface area of MA-700, MA-800, MA-900 are 253.5, 240.9, and 201.5 m²g⁻¹, respectively. The MA-700 shows the highest Mo adsorption capacity of 59.10 mg (Mo)g⁻¹(sample), followed by MA-800 (55.19 mg g⁻¹) and MA-900 (49.91 mg g⁻¹). For the Tc-99m percentages, MA-900 resulted in the optimal yield of 100,33 %, then MA-800 (89.82%), and MA-700(45.96%).

5.2 A Porous Reusable UO₂ Target to Increase the Sustainability of Mo-99 Manufacturing

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The transition from HEU to LEU targets for Mo-99 manufacturing has provided non-proliferation benefits which is a benefit to society. However, the drawback of this transition without any further modification to the target has led to increased volumes of intermediate level nuclear waste both solid and liquid which is a long-term storage issue and an extra cost burden. To minimise the amount of nuclear waste being produced a new type of porous UO₂ target which requires no dissolution is being developed with the possibility to be irradiated and eluted multiple times for reuse in production. Currently MCNP6.2 modelling of various target parameters has been completed and the next stage of physical target development has begun. The extra benefit of this target is that it can be made from natural uranium thus requiring no enrichment process.

5.3 Studies on Production of Mo-99 through Mo-100(γ ,n)Mo-99 Nuclear Reaction in Simulated Processing Conditions

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The essential steps in the production of Mo-99 via Mo-100(γ ,n)Mo-99 nuclear reaction, such as preparation of molybdenum target, dissolution of gram amount of target material, separation of Tc-99m from the excess of molybdenum and recovery of target material after the technological process were investigated. Pressing and sintering metallic molybdenum powder to the form of discs was used as a method of the target preparation. The alkaline dissolution of molybdenum was investigated up to 9 g of target mass. The 15 mL 30% H₂O₂ and 5 mL 5M NaOH/1 g Mo was needed for total dissolution of sintered molybdenum discs. TK 202 resin (TRISKEM Int), highly selective for Tc-99m was used for the separation of Tc-99m from the excess of molybdenum. The simulation of TK 202 resin based reverse Mo-99/Tc-99m generator resulted in 86 ± 2 % elution yield of Tc-99m (n=3). The precipitation of molybdenum oxide with glacial acetic acid was demonstrated to be an effective technique for recovery of molybdenum target material. Although the studies have been performed using simulated conditions, optimized processes constitute the base for establishing a real production technology.

SESSION 6 Regional and Future International Production

Session Chair: Nil Neda Bedro

6.1 IAEA Activities in Support of Production of Mo-99 and Mo-99/Tc-99m Generators

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6.2 Korean Mo-99 Project and New Research Reactor Progress

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In Korea, new research reactor (Kijang Research Reactor: KJRR) project has been launched in 2012 for the domestic and global supply of medical and industrial radioisotopes. In parallel, LEU-based fission Mo-99 process development has been initiated for the KJRR project.

In mid-2022, KAERI started building construction of the new research reactor in the city of Busan aiming its first criticality in 2027. From 2023, KAERI will resume the second-phase Mo-99 process development project for the utilization of the new research reactor.

In this meeting, progress of the Korean Mo-99 project and KJRR construction will be presented.

6.3 Current Status of Mo-99 Production and Future Prospects in Argentina

Natalia Stankevicius

CNEA/ Argentina

SESSION 7 Mo-99 Supply Chain Perspectives

Session Chair: Seung-Kon Lee

7.1 Coordinated International Efforts for a Reliable Supply of Medical Radioisotopes

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Lantheus

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Chairman, Nuclear Medicine Europe, Security of Supply Working Group

Since 2006, the supply chain for the medical isotope Mo-99 and other isotopes has experienced periods of instability due to unplanned outages of key production facilities. International stakeholders including Governments, international organizations, nuclear medicine companies, trade associations, medical societies and others have undertaken intensive efforts to address the root causes and to implement new or strengthened measures to improve reliable supply of Mo-99 and other isotopes. Nuclear Medicine Europe (formerly AIPES) play a lead role in this effort.

The presentation will describe the efforts of Nuclear Medicine Europe to improve international radioisotope supply. Nuclear Medicine Europe has focused on enhancing coordinated industry activities including responses to unforeseen disruptions and improved research reactor scheduling. The presentation will discuss and highlight the Nuclear Medicine Europe Security of Supply Working Group and Emergency Response Team (ERT) in improving international supply of Mo-99, I-131, and future supply of various theranostic isotopes.

7.2 Cardinal Health Nuclear & Precision Health Solutions Perspectives on the Reliable Supply of Molybdenum-99

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Molybdenum-99 (Mo-99) is the parent of the most commonly used radionuclide in nuclear medicine: technetium-99m (Tc-99m). Technetium-99m is used in millions of nuclear medicine imaging procedures each year. Tc-99m has a six-hour half life and must be distributed daily to medical facilities on a just-in-time basis. Disruptions to molybdenum-99 production can lead to a cascading effect throughout the supply chain, ending at a patient awaiting an important imaging procedure.

In the U.S. healthcare system, nuclear pharmacies receive Mo-99/Tc-99m generators and play an essential role in the supply chain with the preparation and distribution of Tc-99m radiopharmaceuticals. This provides nuclear pharmacies with a unique perspective on the challenges involved with ensuring continuity of patient care. With the widespread use of Tc-99m, robustness and resiliency of the Mo-99 supply chain is critical to healthcare.

7.3 Development of Supply Chain Performance Measurement System Based on a Multicriteria Decision Aid Prométhée-II for Mo-99 Integrated Supply Chain

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From production, through transport, and healthcare organisations, to the patient, each entity is part of the Mo-99 supply chain (SC). The integration of actors as a single entity, an inter-organizational process is the essence of Supply Chain Management and aims to improve the performance of the whole chain by focusing on the skillful implementation of the best strategies. A Supply Chain Performance Measurement System based on a multi-criteria tool allows the disparate elements of the Mo-99 SC such as reliability, safety and

security, regulatory, environmental, and social aspects along with technologies challenges to be encompassed in a coherent, cohesive, and dynamic system. The Prométhée II decision support tool, based on pair-wise evaluation enables a straight-forward comparison of scenarios according to the relative importance of each aspect, as assigned by the stakeholders. The methodology is explained, strategies and metrics specific to Mo-99 SC are proposed and the tool is presented.

7.4 My 15 Year Perspective on the Mo-99 Shortage, What Did We Learn?

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In April 2007, the author appeared on behalf of the FDA before the National Academy of Sciences' Committee on "Medical Isotope Production Without Highly Enriched Uranium". The committee had concerns that FDA rules could impede the conversion from highly enriched uranium (HEU) to low enriched uranium (LEU). While attempting to assure the committee to the contrary, the question lingered over the next few years. This meeting was the first of a series of such meetings spanning 15 years, including today's meeting, that affected the author's career. During this period, both as an FDA employee and later as an independent consultant, he has worked with many individuals advising on FDA rules and policies. These individuals represented domestic and international governments, professional organizations, and industry. In this presentation, he will present his opinion of the underlying causes of the shortage, the solutions, and his perception of the future.

SESSION 8 Regulating and Enabling Mo-99 Production

Session Chair: Hertzog Bissett

8.1 Regulatory Considerations in the U.S. on Mo-99 produced by LEU and Novel Technologies

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The FDA will discuss quality standards and regulations relevant to the approval of Tc-99m produced from Mo-99 derived from LEU and novel technologies. The approval of the radiogenix system, a novel Tc 99m generator, is an example of effective U.S. government interagency collaboration with the regulated industry and other stakeholders to bring the novel technology to patients. Multidisciplinary technical assessment within FDA led to a novel approach to regulation and safe use of the product. Challenges with medical isotope supply chains derived from fission and novel processes and response from regulators will be discussed.

8.2 ESA Activities to Support the Secure Supply of Medical Radioisotopes in the EU

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The mission of the Euratom Supply Agency (ESA) is to maintain regular and equitable supply of nuclear materials for all users in the EU. The strategic objective is the security of supply of nuclear materials for power and non-power uses, by means of the common supply policy.

In 2013, the role of ESA was enlarged to cover the aspects of the supply of medical radioisotopes. Since then, ESA has co-chaired with the nuclear medicine industry organization for Europe (NMEu) the European Observatory on the Supply of Medical Radioisotopes, which brings together representatives of the European Commission,

international organisations and industry. The Observatory monitors the EU supply chain of Mo-99/Tc-99m and engages on a variety of topics on the supply of other widely used medical radioisotopes.

In line with its strategic objective and the 2021 European Commission's Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA), which is the energy sector's contribution to Europe's Beating Cancer Plan, ESA also scrutinises the security of supply of HEU and HALEU, which are required to produce medical radioisotopes and to fuel research reactors.

ESA assists with the supply of HEU to users who still need it until they convert to HALEU, in line with international nuclear security and non-proliferation commitments. In close cooperation with the Euratom Member States, the Agency renewed in 2021 for the next 5 years the Memorandum of Understanding (signed in 2014) with the U.S. National Nuclear Security Administration for the exchange of HEU for European research reactors and medical radioisotope production facilities.

In 2021, the ESA Advisory Committee dedicated working group on HALEU was reinstated to respond to the EU's need for research reactor fuel and medical radioisotopes production by exploring industrial and commercial options to build a European capacity for producing HALEU metal. In 2022, the working group delivered a report, which provides an updated view of HALEU needs, including potential EU and global demand and presents three options to provide a security of HALEU supply in the EU.

8.3 Licensing and Oversight of Mo-99 Programs at the U.S. Nuclear Regulatory Commission

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8.4 Source Term Analysis of Xenon (STAX) Project, A Collaboration Between Medical Isotope Production and Nuclear Explosion Monitoring Communities

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The "Source Term Analysis of Xenon" (STAX) project is a United States initiative to support the Preparatory Commission for the Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO PrepCom) by providing nuclear detectors to medical isotope production facilities that measure effluents from the stacks of nuclear facilities that emit radioactive xenon. The scientific community has identified radioactive xenon emissions from nuclear facilities as the dominant background source to nuclear explosion monitoring such as that performed by the International Monitoring System (IMS) which was designed and constructed for the verification of the Comprehensive Nuclear-Test-Ban Treaty. While the amount of radioactive xenon emitted by facilities are known to not harm the environment or pose any hazard to the population, the radioactive isotopes emitted are frequently detected by the ultra-sensitive IMS. The goal of the STAX project is to determine how emissions data from nuclear facilities can be used to better understand the global xenon background.

SESSION 9 Technology Development Updates II

Session Chair: Kyle Sallee

9.1 General Precautions Related to Preparation and Use of Mo-99/Tc-99m Generators Based on Alumina Chromatographic Columns

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It is well known that Tc-99m is the most extensively used radioisotope in nuclear medicine for the purpose of performing a wide variety of imaging studies. As Mo-99/Tc-99m alumina column generator is the main source of Tc-99m, it is essential to take into consideration the parameters affecting the eluted Tc-99m activity and the subsequent different radiolabeling processes in order to reach the optimum preparation and use of such generators. Those parameters include Tc-99m species, elution time and mechanical problems. In addition, routine production of Mo-99/Tc-99m generators requires a valid calculation model to predict the eluted activity of Tc-99m on calibration date, using the measured eluted Tc-99m activity (at any time between production and calibration dates), taking into account time elapsed between: (i) conditioning and elution and (ii) elution and measurement.

9.2 Development of a Plasma-Aided Fluorination Process for Mo-99 Separation

T. Chemnitz and W. Petry

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To enhance Mo-99 extraction and reduce the volume of waste associated with its production, we are currently developing a dry-chemical process for its separation from irradiated U-235. This process is based on the use of monolithic U-235 targets, their subsequent plasma-aided fluorination and the photochemical treatment of the formed hexafluorides. A sputtering process allows the fabrication of cylindrical monolithic LEU foil targets theoretically containing up to 16 g/cm³ uranium enriched to 19.75 %. A mechanical separation of these foils from their inner aluminum cladding avoids the use of an alkaline digestion. The then accessible foils are fluorinated in a plasma process using NF₃ as an etching agent. As molybdenum and uranium both form volatile hexafluorides, they can easily be separated from non-volatile fluorides of other fission and decay products. After this physical separation, an additional chemical separation step is introduced using selective UV-induced photo-dissociation in supercritical CO.

9.3 Summary and Outcomes of IAEA CRP on “New Ways of Producing Tc-99m and Tc-99m Generators”

Aruna Korde, Mark De Jong, Xiang Gao, Sankha Chattopadhyay, Marlina Marlina, Hossein Khalafi, Jaewoong Jang, Muhammad Asif, Pablo Antonio Mendoza Hidalgo, Przemysław Koźmiński, Izabela Cieszykowska, Dana Niculae, Jan Rijn Zeevaart, Mykola Dykyi, Sergey Chemerisov, Amir Jalilian, Valeriia Starovoitova, Joao Alberto Osso Jr, Celina Horak, Melissa Denecke