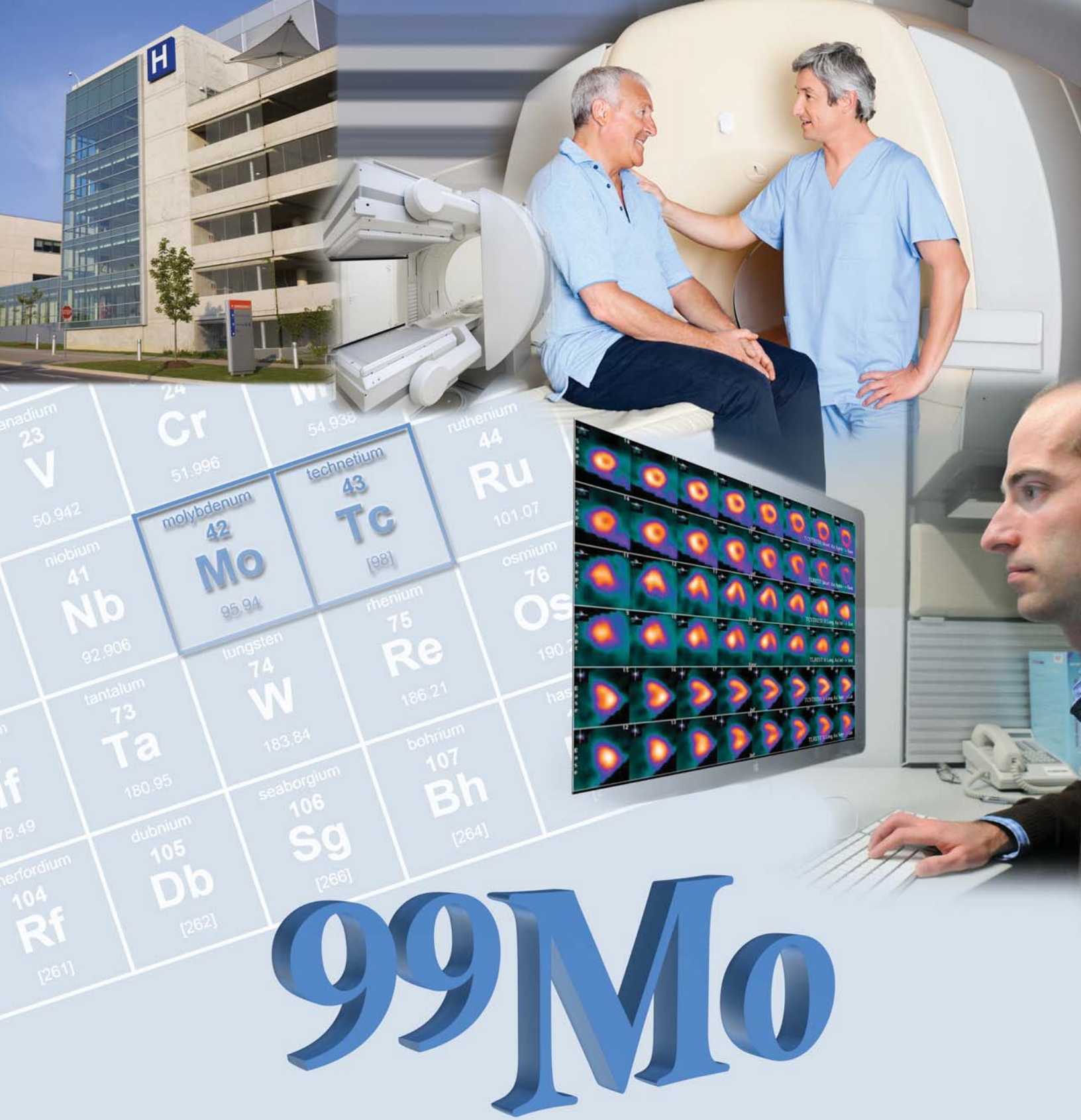
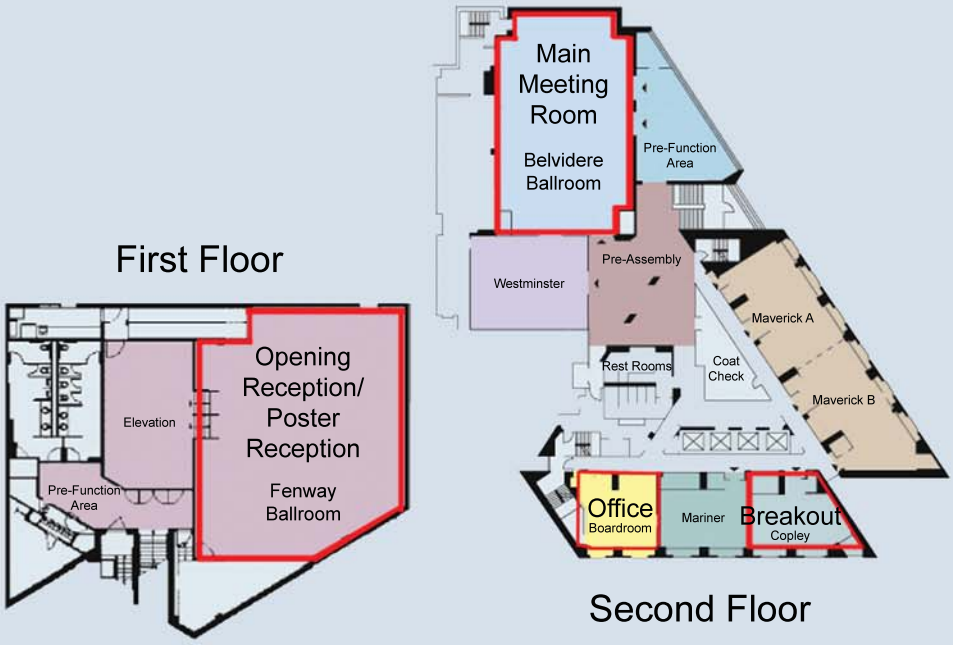


Topical Meeting

Boston, Massachusetts • August 31 - September 3, 2015

ANS

Meeting Space Map
Hilton Boston Back Bay



99Mo 2015 Topical Meeting • Program

#	Session Title	Time	Topic	Presenter
Monday, August 31 Registration: 4:30 pm - 6:00 pm, Fenway Pre-Function Area Welcome Reception: 6:00 pm - 7:30 pm, Fenway Ballroom				
Tuesday, September 1 Meeting Room: Belvidere Ballroom				
1	**Opening Plenary Session: Supporting a Reliable, Non-HEU Mo-99 Supply** **MC: Jeff Chamberlin**	9:00 am	DOE-NNSA Welcome	P. Hanlon (DOE-NNSA)
			The Supply of Molybdenum-99 and U.S Government Role	K. Cutler (OSTP)
			Assurance of Supply: Practical Measures, Predictable Actions	A. Paterson (ANSTO)
			"Deflating" the Nuclear Threat – the LEU Goal Line is in Sight!	W. Dawes (LMI)
10:00 am Coffee Break and Refreshments				
2	**Progress Toward Sustainable Supplies of Non-HEU Mo-99 – Session I** **Session Chair: Michael Guastella**	10:30 am	Status of the HLG-MR	P. Staples (DOE-NNSA)
			European Union's Efforts to Sustain the Supply of Mo-99 - An Update	S. Tsalas (ESA)
			Report from the NSAC Mo-99 Subcommittee	S.J. Seestrom (NSAC Mo-99 Committee, LANL)
			State of Molybdenum-99 Production and Utilization and Progress toward Eliminating Use of Highly Enriched Uranium	T.J. Ruth (NAS)
			Reflections on Five Years of Conversion Experience	G. Ball (NTP)
12:00 pm Lunch Break				
3	**Medical Community Perspectives** **Session Chair: Parrish Staples**	1:30 pm	SNMMI Ongoing Efforts to Support Reliable Supplies of Mo-99 Produced Without HEU	S.W. Schwarz (SNMMI)
			Myocardial Perfusion Imaging: Current State and Future Need of Tc99m	M.F. Di Carli (Brigham and Women's Hospital)
			A Survey of Active Clinical Trials Using SPECT Imaging	J. Norenberg (UNM)
			Managing the Paradigm Shift: Demand and Utilization of SPECT MPI in an Era of Value Based Payment	G. Hearn (ASNC)
			The Future of Nuclear Medicine Services: Reimbursement Challenges Updated	D. Merlino (Merlino Healthcare Consulting)
3:00 pm Coffee Break and Refreshments				
4	**Progress Toward Sustainable Supplies of Non-HEU Mo-99 – Session II** **Session Chair: Joanie Dix**	3:30 pm	OECD-NEA Update, ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2015-2020	K. Charlton (OECD)
			DOE Support for Mo-99 Production in the United States	R. Howell (DOE-NNSA)
			Nuclear Pharmacy Practice Issues: Cardinal Health Perspective	S. Claunch (Cardinal Health)
			Irradiation of LEU Targets in the BR2 Reactor for Mo-99 Production	B. Ponsard (SCK•CEN)
			Status of the Uranium Lease and Take Back Program	P. Karcz (DOE-NNSA) H. Nigam (DOE)
			Plans for Developing the U.S. Department of Energy's Enriched Stable Isotope Production Facility	D. Phillips (DOE)
5:30 pm Adjourn				

Wednesday, September 2 Meeting Room: Belvidere Ballroom				
#	**Session Title**	**Time**	**Topic**	**Presenter**
5	**Radiopharmacy Perspectives** **Session Chair:** **Dennis Phillips**	8:30 am	The Role Group Purchasing Organizations Take in Embracing the Transition to Non-HEU Medical Isotopes	L. Gannon (Novation)
			Triad Isotopes, Inc. Perspectives on Nuclear Pharmacy's Role in the use of Non-HEU Mo-99 for Tc-99m Compounded Patient Preparations	F. Gattas (Triad Isotopes)
			UPPI LEU Walk: The Difficulty Intersecting Strategies Pose in the Transition to non-HEU Medical Radiopharmaceuticals	J. Witkowski (UPPI)
			Stakeholder Outreach for Reliable Supply of Mo-99 and LEU Conversion	J. Hinkle (GE Healthcare)
			Challenges of Marketing LEU (One Year Later)	C. Gray (West Coast)
10:00 am Coffee Break and Refreshments				
6	**Current and Future Supply Chain Outlook - I** **Session Chair:** **Valery Host**	10:30 am	Update on Mallinckrodt's Conversion to LEU Production of Mo-99	R.W. Brown (Mallinckrodt)
			Recent Developments in Perma-Fix Medical's Tc-99 Production	L. Centofanti (Perma-Fix)
			MARIA Research Reactor in Supply Chain of Mo-99	G. Krzysztoszek (NCBJ)
			Northwest Medical Isotopes, LLC Project Overview and Status	C. Haass (Northwest Medical Isotopes, LLC)
			Towards Domestic Production of Mo-99	J.T. Harvey (NorthStar)
			Niowave's Domestic Production of Mo-99 from Uranium to Start in 2015	T.L. Grimm (Niowave, Inc.)
12:30 pm Lunch Break				
7	**Regulatory Perspectives** **Session Chair:** **Carolyn Haass**	2:00 pm	U.S. Nuclear Regulatory Commission Licensing Activities Related to Molybdenum-99	M.F. Balazik (NRC)
			Impact of High Cost Mo-99 on Healthcare Reimbursement Models	D. Duvall (CMS)
			FDA Activities Promoting Mo-99 Production from non-HEU Processes and Assuring Mo-99 Supply	E. Duffy (FDA)
			U.S. Nuclear Regulatory Commission Environmental Reviews Related to Molybdenum 99 Production	M.R. Moser (NRC)
3:00 pm Coffee Break and Refreshments				
8	**Current and Future Supply Chain Outlook - II** **Session Chair:** **Tom Burnett**	3:30 pm	Update on LEU TechneLite® Generators	I.N. Goldman (LMI)
			ANSTO Nuclear Medicine Mo-99 Facility	D. Cubbin (ANSTO)
			Recent Achievements of IRE's LEU Conversion Project	V. Host (IRE)
			Considerations Regarding Full Cost Recovery in Direct Production of Tc-99m	K.R. Buckley (ITAP)
			Next Generation Mo-99 Production: SHINE Update	K.M. Pitas (SHINE)
			Selective Gas Extraction: A Transformational Production Technology being Implemented by GA, MURR and Nordion	C. Critch (Nordion) J. Saurwein (GA) K. Brooks (MURR)
5:30 pm Break: Setup Posters, Fenway Ballroom 6:00 pm Poster Session and Reception				

Wednesday, September 2 (continued) Meeting Room: Fenway Ballroom				
#	**Session Title**	**Time**	**Topic**	**Presenter**
9	**Poster Session and Reception** **MC:** **Rilla Hamilton**	6:00 pm	Removal of Tc from Neutron-Capture 99Mo using Eichrom's ABEC Resin	M.E. Bennett (ANL)
			Collaborative Efforts between the Medical Isotope Production and the Nuclear Explosion Monitoring Communities	C.G. Doll (PNNL)
			Design of High Power Beam Dump and Collimator	R. Gromov (ANL)
			UAlx Phase Analysis on the LEU Dispersion Targets with Changing the Composition of Atomized UAlx Powders	Y.J. Jeong (KAERI)
			Update on IAEA Activities Supporting Non-HEU Production of Mo-99 & Tc-99m	J. Dix (IAEA)
			Development of Atomized UAlx Powder for Mo-99 Target Fabrication	K.N. Kim (KAERI)
			Scalability of the LEU-Modified Cintichem Process	D.A. Rotsch (ANL)
			Robust Medical Isotope Production System	S. Klein (LANL)
			Generation of Gas Bubbles in a Fissioning Uranyl Sulfate Solution Using an Electron Beam Linac	T.A. Heltemes (ANL)
			Design of a Tritium Purification Process for SHINE Mo-99 Production	D. Babineau (SRNL)
			Experience of LEU Mo-99 Production with the MINI-LOOP System	D. Amaya (INVAP)
7:30 pm Adjourn				

Thursday, September 3 Meeting Room: Belvidere Ballroom				
#	**Session Title**	**Time**	**Topic**	**Presenter**
10	**Technology Development – I** **Session Chair:** **Chris Bryan**	8:30 am	SHINE Chemistry Overview	A. Youker (ANL)
			PVD-based Manufacturing Process of Monolithic LEU Foil Targets for 99Mo	T. Hollmer (FRM II)
			Engineering and Design Activities at Los Alamos National Laboratory Supporting Commercial U.S. Production of Mo-99 without the Use of HEU	G. Dale (LANL)
			Feasibility of Transmutational Production and Magnetic Extraction of Moly-99 via 1-neutron Knockout and Exchange Reactions in Auto-colliding Beam of Natural Mo Ions in Strong-focusing Precetron ("EXYDER") and Electric Energy Recuperation by Ion Decelerator	B.C. Maglich (CSEC)
			Corrosion Assessment of Candidate Materials for the SHINE Subcritical Assembly Vessel and Components	S.J. Pawel (ORNL)
10:00 am Coffee Break and Refreshments				

Thursday, September 3 (continued) Meeting Room: Belvidere Ballroom				
#	**Session Title**	**Time**	**Topic**	**Presenter**
11	**Technology Development – II** **Session Chair: Thad Heltemes**	10:30 am	Development of Accelerator Based Production of Mo-99	S.D. Chemerisov (ANL)
			Powder Metallurgy Fabrication of Molybdenum Target Materials and Assemblies	R.A. Lowden (ORNL)
			100Mo to 99Mo Production Target: Design Status and Test Results	K. Woloshun (LANL)
			Chemical Processing Activities for Mo-99 production by (γ,n) and (n,γ) reactions using enriched 100Mo and Mo-98 targets	P. Tkac (ANL)
			Neutron Irradiation Testing of Structural Components in Support of an Accelerator Driven Subcritical Assembly for the Production of Mo-99	J.W. Geringer (ORNL)
12	**Summary and Closure, 12:00 pm** **MC: Jeff Chamberlin**			
12:30 pm Adjourn				
Optional Technical Tour of Lantheus Medical Imaging Facility *(Bus transportation provided)* 2:30 - 5:30 pm				

SESSION ABSTRACTS

SESSION 1

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

MC: Jeff Chamberlin

1.1 DOE-NNSA Welcome

Peter Hanlon
Assistant Deputy Administrator, Office of Material Management & Minimization
National Nuclear Security Administration, Department of Energy
1000 Independence Ave, Washington, DC 20585 – USA

1.2 The Supply of Molybdenum-99 and U.S. Government Role

Kirsten Cutler
Assistant Director, Nuclear Energy and Non-proliferation
Office of Science and Technology Policy
Eisenhower Executive Office Building, 1650 Pennsylvania Ave, Washington, DC 20504

1.3 Assurance of Supply: Practical Measures, Predictable Actions

Adrian Paterson, CEO
Australian Nuclear Science and Technology Organization (ANSTO)
New Illawarra Rd, Lucas Heights, NSW 2232 – Australia

1.4 "Deflating" the Nuclear Threat – the LEU Goal Line is in Sight!

William Dawes
Vice President, Manufacturing and Operations
Lantheus Medical Imaging, Inc.
331 Treble Cove Rd., N. Billerica, MA 01862 – USA

SESSION 2

Progress Toward Sustainable Supplies of Non-HEU Mo-99
Session I

Session Chair: Michael Gaustella

2.1 Status of the HLG-MR

Parrish Staples
Director, Domestic Uranium Enrichment
National Nuclear Security Administration, Department of Energy
1000 Independence Ave, Washington DC 20585 – USA

This presentation will cover the development of, as well as status and activities of the High Level Group –Medical Radioisotopes (HLG-MR) operated within the Organization for Economic Co-operation and Development Nuclear Energy Agency (OECD/NEA). This group is recommending, coordinating and assessing participating government actions and policies to ensure the long term and reliable supply of the medical isotope ^{99}Mo for patients globally. The HLG-MR general terms of reference include:

- Review the total ^{99}Mo supply chain from uranium procurement for targets to patient delivery and identify weak points and issues.
- Recommend options to address the vulnerabilities to help ensure a stable and reliable supply of radioisotopes.
- Work with supply chain participants to implement policy recommendations developed under the first HLG-MR mandate.
- Work with all components of the industry, including governments and the medical community, to ensure communication about and to address issues concerning implementation of the policy approach.

2.2 European Union's Efforts to Sustain the Supply of Mo-99 – An Update

Stamatios Tsalas
Director General
Euratom Supply Agency
Complexe Euroforum, 10, rue Robert Stumper, L - 2557 – Luxembourg

2.3 Report from the NSAC Mo-99 Subcommittee

S.J. Seestrom
Physics Division, NSAC Mo-99 Committee
Los Alamos National Laboratory, P.O. Box 1663, Los Alamos, NM 87544 – USA

I will present a summary of the most recent report of the NSAC Mo-99 Sub-committee. We have been charged to review the NNSA Mo-99 program. We recently submitted our final report for 2015 to the Department of Energy. I will talk about our process, findings, and recommendations.

2.4 State of Molybdenum-99 Production and Utilization and Progress toward Eliminating Use of Highly Enriched Uranium

T.J Ruth, vice-chair, The National Academies of Sciences, Engineering, and Medicine
Committee on State of Molybdenum-99 Production and Utilization and Progress toward Eliminating Use of Highly Enriched Uranium
The National Academies of Sciences, Engineering, and Medicine
500 5th Street NW, Washington, DC 20001 – USA

Congress has requested an independent assessment from the Academies on the state of molybdenum-99 production and utilization and progress toward eliminating use of highly enriched uranium. The study has the following five tasks:

1. A list of facilities that produce molybdenum-99 for medical use.
2. A review of international production of molybdenum-99 over the previous 5 years.
3. An assessment of progress made in the previous 5 years toward establishing domestic production of molybdenum-99.
4. The adequacy of molybdenum-99 supplies to meet future domestic medical needs.
5. An assessment of the progress made by the Department of Energy and others to eliminate worldwide use of highly enriched uranium in reactor targets and medical isotope production facilities.

2.5 Reflections on Five Years of Conversion Experience

Gavin Ball
General Manager: Production Operations
NTP Radioisotopes SOC Ltd, PO Box 582, Pretoria, 0001 – South Africa

The SAFARI-1 research reactor and NTP ^{99}Mo production facilities at Pelindaba continue to produce and distribute significant quantities of ^{99}Mo for the world nuclear medicine market. Since commencing the development of an LEU based ^{99}Mo production process in early 2007 and the achievement of the first successful large scale LEU ^{99}Mo production in 2010, NTP has continued, together with its customers, with efforts to fully convert from HEU to LEU. Although the uptake of LEU based ^{99}Mo continues to be slower than expected, steady progress continues to be made.

The economics of the ^{99}Mo supply chain remain cause for concern with the critically important ^{99m}Tc isotope continuing to be significantly undervalued. Added to this, the uncertainty and possibly unrealistic time frames of the proposed new production entrants could justifiably pose questions on the longer term sustainability of the industry.

As early as 2010, NTP together with its long standing supply partners have implemented a realistic strategy to ensure reliable supply of ^{99}Mo post 2016 and long term sustainability of the SPECT-based nuclear medicine.

This presentation provides a status update on the conversion project at NTP and reflects on the experiences of the past 5 years while questioning the risks facing the industry in the future.

SESSION 3

Medical Community Perspectives

Session Chair: Parrish Staples

3.1 SNMMI Ongoing Efforts to Support Reliable Supplies of Mo-99 Produced Without HEU

Sally W. Schwarz, RPh, MS, BCNP
President Elect SNMMI
1850 Samuel Morse Drive, Reston, VA 20190 – USA

There are millions of diagnostic nuclear medicine imaging studies performed each year and Technetium-99m is used in 80 % of these studies. The US consumes approximately one-half of the world's supply of Mo-99, but currently has no domestic source. Supply interruptions of Mo-99 would, in many cases, result in patients receiving tests that are less accurate, more costly and have higher doses of radiation. The American Medical Isotopes Production Act (AMIPA) required conversion from HEU to non-HEU Mo-99 production by 2020. Further, it requires a domestic source of Mo-99 be developed. DOE has partnered with US commercial entities since 2009 to accelerate development of non-HEU technologies to produce US based Mo-99. Implementation of the AMIPA may be delayed if there remains insufficient global supply of non-HEU Mo-99 to satisfy domestic use. Companies have increased production and outage reserve capacity in order to maintain a stable supply. SNMMI continues its advocacy to assure that all stakeholders continue to work together to ensure a stable supply. SNMMI also continues to work with Medicare (CMS) and others to achieve adequate and appropriate reimbursement.

3.2 Myocardial Perfusion Imaging: Current State and Future Need of ^{99m}Tc

Marcelo Fernando Di Carli
Associate Radiologist, Brigham and Women's Hospital
Professor of Radiology, Harvard Medical School
Department of Radiology, 75 Francis Street, Boston, MA 02115 – USA

3.3 A Survey of Active Clinical Trials Using SPECT Imaging

Jeffrey P. Norenberg[1, 2], Robert W. Atcher[1, 3]
1. Radiopharmaceutical Sciences Program, College of Pharmacy, University of New Mexico Health Sciences Center, Albuquerque, NM 87131-0001 – USA
2. Department of Anesthesiology & Critical Care Medicine, School of Medicine, University of New Mexico Health Sciences Center., Albuquerque, NM 87131-0001 – USA
3. Los Alamos National Laboratory, Los Alamos, NM 87545 – USA

The focus on the impact of the shortages of ^{99}Mo/^{99m}Tc has been on its use in diagnostic nuclear medicine. One half of the world-wide consumption of ^{99m}Tc is in the US, and half of that is used in cardiac imaging. Less appreciated is the role that ^{99m}Tc radiopharmaceuticals play in clinical trials. According to clinicaltrials.gov 511 studies use SPECT imaging in their protocol. Of these 311 studies cite the use of ^{99m}Tc in the study; 101 are listed as open to accrual. These trials include: the evaluation of novel ^{99m}Tc radiopharmaceuticals; the diagnostic utility of images acquired using lower doses of ^{99m}Tc compounds; comparative studies with the new PET imaging agents; and SPECT imaging to monitor the effectiveness of new therapies to a variety of diseases. This report provides insights into the various approaches that utilize ^{99m}Tc and highlight some important studies aimed at advancing diagnostic imaging therapeutic medicine.

3.4 Managing the Paradigm Shift: Demand and Utilization of SPECT MPI in an Era of Value Based Payment

Georgia L. Hearn, JD
Senior Specialist, Regulatory Affairs
American Society of Nuclear Cardiology
4340 East-West Highway, Suite 1120, Bethesda, MD 20814 – USA

The American Society of Nuclear Cardiology is comprised of 4,500 practicing nuclear cardiologists. As the end users of Mo-99 our membership is uniquely interested in ensuring that there is a stable supply of Mo-99 and is supportive of effort to move to non-HEU sources of molybdenum. ASNC believes a number of factors will influence demand for MPI in the coming years of particular concern to our membership is the prevalence of other modalities that may not provide the same exacting clinical information but that physicians may shift to perform in greater numbers because they do have barriers in terms of isotope supply. In addition, as baby boomers age the Medicare population is projected to increase exponentially driving the utilization of

SPECT MPI higher. However, this growth will be tempered by a new, more restrictive payment policy by both Medicare and private payers (see, e.g. the Appropriate Use Mandate Program contained in the Protecting Access to Medicare Act of 2014 and RBM/Private Payer Policies).

3.5 The Future of Nuclear Medicine Services: Reimbursement Challenges Updated

Denise A. Merlino
President
Merlino Health Care Consulting Corp.
P.O. Box 5569, Magnolia, MA 01930-0008 – USA

SESSION 4

Progress Toward Sustainable Supplies of Non-HEU Mo-99 Session II

Session Chair: Joanie Dix

4.1 OECD-NEA Update, ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2015-2020

Kevin Charlton
Nuclear Development Division
OECD Nuclear Energy Agency
12, boulevard des Îles, 92130 Issy-les-Moulineaux – France

4.2 DOE Support for Mo-99 Production in the United States

Randy A. Howell
DOE/NNSA
1000 Independence Ave, Washington, DC 20585 – USA

The Department of Energy's Mo-99 Program implements the mandate of the American Medical Isotope Production Act of 2012 to support commercial projects for the production of molybdenum-99 in the United States without the use of highly enriched uranium. The Program provides financial and technical support to multiple partners for the development of their projects, which each use a different technical approach to Mo-99 production. This presentation will summarize Program activities and updates since the last Mo-99 Topical Meeting.

4.3 Challenges Marketing LEU (One Year Later)

Cal Gray R.Ph., N.P.
President
West Coast Nuclear Pharmacy, LLC, 3906 Cragmont Drive, Tampa, FL 33619 – USA

The American Medical Isotopes Production Act promotes the transition of radiopharmaceuticals manufactured from HEU sources to those produced by non-HEU methods. The radiopharmacy plays a key role as the driver of the initial conversion, the source for bringing the physicians together as stakeholders and in delivering patient doses of non-HEU radiopharmaceuticals to the molecular imaging community. One year invested after the industry adoption of non-HEUMo99 generators two years earlier, the transition in the community is less than 10%. Challenges to adapting its clients and to complete the transition in the local market are still a challenge even as the pipeline of non-HEU becomes more robust. New factors and drivers are identified going forward and the considerations that should be understood as Full Cost Recovery becomes fact.

4.4 Irradiation of LEU Targets in the BR2 Reactor for Mo-99 Production

Bernard Ponsard
Radioisotopes Project Manager
BR2 Reactor
Belgian Nuclear Research Centre (SCK•CEN), Boeretang 200, B-2400 Mol – Belgium

The BR2 reactor has currently with 7.800 six-day curies per week the largest installed irradiation capacity worldwide for the production of Mo-99. This production level is currently achieved by the irradiation of highly enriched uranium (HEU) targets in dedicated irradiation devices. In support of non-proliferation objectives and global reliability of supply, two separate projects have been initiated in 2012 with the processors IRE and MALLINCKRODT to develop low enriched uranium (LEU) targets for the production of Mo-99 without the use of HEU. The safety approval for 'test' irradiations has been received after submission and analysis of the safety report including neutronic calculations, thermohydraulic calculations, modification of existing irradiation devices and updated irradiation procedures. Five irradiation campaigns of LEU targets have been successfully performed in the BR2 reactor in 2014 before its refurbishment for a period of 16 months (February 2015 – June 2016) which will enable safe and reliable operation of the reactor for another period of at least 10 years. SCK•CEN is considering upgrading BR2's operating regime and increasing its yearly irradiation capacity for Mo-99 production if compatible with the full-cost recovery principle defined by OECD/NEA's High-Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR).

4.5 Status of the Uranium Lease and Take Back Program

P.J. Karcz
DOE/NNSA
1000 Independence Ave, Washington, DC 20585 – USA

4.6 Plans for Developing the U.S. Department of Energy's Enriched Stable Isotope Production Facility

J.P. Grimm
Office of Science, U.S. Department of Energy
1000 Independence Ave. SW, Washington, DC 20585 – USA

Enriched molybdenum isotopes may play an important role in the future supply chain of Tc-99m radiopharmaceuticals. The U.S. Department of Energy is developing a new domestic capability to provide enriched stable isotopes. The Enriched Stable Isotope Pilot Facility (ESIPF), located at Oak Ridge National Laboratory, will include a modest gas centrifuge cascade and one electromagnetic separator. The objective is to provide small quantities of high priority enriched isotopes for research and applications, and also replenish DOE's Isotope Program inventory. This will allow the Isotope Program to support ongoing research and commercial applications requiring only milligram- to gram-size quantities of enriched isotopes. The development work is planned to be complete in FY 2016. During 2017 and 2018, DOE plans to conduct isotope production runs to provide modest new inventories for sale. Operating experience will be assessed to strategize for expanded production capacity in the future.

SESSION 5

Radiopharmacy Perspectives

Session Chair: Dennis Phillips

5.1 The Role Group Purchasing Organizations Take in Embracing the Transition to Non-HEU Medical Isotopes

Leah Gannon
Pharmacy Portfolio Executive
Novation, 290 E John Carpenter Frwy, Irving, TX 75062 – USA

Novation, the nation's leading health care contracting and information service company plays a key role in the healthcare supply chain through various contracting, advocacy and solution strategies that advance high quality and cost-effective care provided by its more than 100,000 members and affiliates of VHA Inc., UHC, Children's Hospital Association and Provista LLC. It is widely predicted that full cost recovery of non-HEU together with the additional costs of new

technologies will increase overall healthcare costs related to nuclear medicine. Novation is uniquely positioned to help educate and promote new market technologies, such as a sustainable and reliable domestic supply of non-HEU products, while also providing a unified voice for healthcare providers. Novation plays a key role in partnering with healthcare providers and other stakeholders to facilitate solutions that will continue to drive efficiencies within the healthcare supply chain and clinical operations. Through actively engaging stakeholders, Novation helps drive costs out of the system while facilitating clinical excellence, and supports members in their pursuit of optimal reimbursement from payers.

5.2 Triad Isotopes, Inc. Perspectives on Nuclear Pharmacy's Role in the use of Non-HEU Mo-99 for Tc-99m Compounded Patient Preparations

Fred Gattas, Pharm. D.
BCNP, FAPhA Director, Quality and Safety
Triad Isotopes, Inc. 4205 Vineland Rd., Ste. L1, Orlando, FL 32811 – USA

The American Medical Isotope Production Act was enacted to promote the production of non-highly enriched uranium (non-HEU) Molybdenum-99 in the United States. The nuclear pharmacy has a very important role in this by dispensing radiopharmaceutical preparations that have been compounded using ingredients exclusively from non-HEU Mo-99; specifically, the daughter isotope Tc-99m, which the nuclear pharmacist binds to various pharmaceutical ligands for use in a myriad of patient diagnostic scans.

A variety of logistical problem-solving challenges arise during the period of transition from use of HEU to non-HEU products, specifically: procuring an ample supply of non-HEU Mo-99/Tc-99m generators; tracking the Tc-99m elutions from those generators; tracking the compounded Tc-99m kits prepared from those elutions; and tracking and ensuring that individual patient doses from those kits are properly labeled. Ensuring that efficient and economical use of non-HEU inventory is balanced with demand from the nuclear medicine community is important as well.

5.3 UPPI LEU Walk: The Difficulty Intersecting Strategies Pose in the Transition to Non-HEU Medical Radiopharmaceuticals

John Witkowski
President, UPPI, LLC
5400 Laurel Springs Parkway Suite 405, Suwanee, GA 30024 – USA

The radiopharmacy network of UPPI is 'actionable' to place and promote the transition of radiopharmaceuticals manufactured from HEU sources to those by non-HEU (or LEU) production methods. Beyond the important role in delivering patient doses of non-HEU radiopharmaceuticals to the molecular imaging community, UPPI via its LEU Walk has developed solutions to difficulties which arose from parallel strategies of Mo 99 stakeholders and those who should become stakeholders. Key to being actionable is the development of broader solutions that keep the transition moving forward. Challenges are presented when

working with Hospital Group Purchasing Organizations, Hospital Supply Chain, material management and others interested parties in understanding the impact that the principle of Full Cost Recovery will have on the market space.

5.4 Stakeholder Outreach for Reliable Supply of Mo-99 and LEU Conversion

Jessica Hinkle
GE Healthcare
Life Sciences Core Imaging and InVitro Diagnostics Sourcing
3350 North Ridge Ave., Arlington Heights, IL 60004 – USA

GE Healthcare (GEHC) has been integrally involved in building and maintaining a stable Supply Chain for Molybdenum-99 (Mo-99) both as a manufacturer of Technetium-99 (Tc-99) generators, as well as a distributor of patient doses through GE's US radiopharmacies. GEHC continues to be a strong supporter of transitioning from HEU to LEU material. Today, we are actively working on validations in order to use Mo-99 generated from LEU in our Drytec generators. Additionally, a significant focus has been placed on ensuring our radiopharmacies have robust systems to adequately track the distribution of LEU doses as we begin to fully convert our pharmacies.

In order to ensure the continued reliable supply of this medical isotope, GE has contractual relationships with both Lantheus and Mallinckrodt, actively is communicating with customers to ensure they are aware of the impact associated with the shift to LEU and continues to support alternative technologies, which do not utilize HEU starting materials.

It is GE's priority to ensure awareness of the key challenges with the current Mo-99 Supply Chain, as well as mitigate to the best of our abilities any supply disruptions. We continue to invest in the future of Nuclear Medicine as well as work to improve communication and efficiencies for the community.

5.5 Nuclear Pharmacy Practice Issues: Cardinal Health Perspective

S. Claunch
Cardinal Health
7000 Cardinal Place, Dublin, OH 43017 – USA

SESSION 6

Current and Future Supply Chain Outlook – Session I

Session Chair: Valery Host

6.1 Update on Mallinckrodt's Conversion to LEU Production of Mo-99

R.W. Brown
Government Affairs
Mallinckrodt Pharmaceuticals, 675 McDonnell Blvd., Hazelwood, MO 63042 – USA

Conversion from the use of High Enriched Uranium (HEU) to Low Enriched Uranium (LEU) targets for the production of Mo-99 is critical for the long term sustainability of the nuclear medicine industry. Mallinckrodt has been a major producer of Mo-99 from its facility in the Netherlands for more than 25 years. The conversion to the use of LEU targets began in 2010 and is nearing completion. Several technical and regulatory challenges arose during the process development stages, which are all being addressed. Although conversion to the use of LEU is expected by the end of 2017, drug regulatory approvals still need to be obtained in all the countries in which Mallinckrodt produced Mo-99 in Tc-99m generators will be sold.

6.2 Recent Developments in Perma-Fix Medical's Tc-99 Production

L. Centofanti
Perma-Fix Medical SA
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Perma-Fix Medical SA has developed a $^{99}Mo/^{99m}Tc$ generator based on molybdenum (n,y) using a novel micro-porous composite (MPCM) resin as an adsorbent. The MPCM resin is found to be capable of adsorbing > 60 wt% molybdenum of its body weight at solution pH 3.0. Recent test confirms that the company's proprietary resins could withstand higher levels of radiation, up to 6 Curies (1.5 Ci/gram of resin), while producing clinically useful doses of ^{99m}Tc. The effect of different operating parameters to demonstrate a prototype $^{99}Mo/^{99m}Tc$ generator was also investigated. ^{99m}Tc, the decay product of ^{99}Mo, was eluted mainly with saline solution (0.9% NaCl). The elution contains a yield of > 80% of the theoretical amount of ^{99m}Tc available from the ^{99}Mo over the life of the generator. The breakthrough of ^{99}Mo and the pH of the eluent that pass through an alumina guard column are within the USP and EUP limits.

6.3 MARIA Research Reactor in Supply Chain of Mo-99

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The high flux research reactor MARIA is operated at the National Centre for Nuclear Research. Due to supply shortages of molybdenum-99 during July 2009 – February 2010 there was developed the Mo-99 irradiation and transport technology in MARIA reactor facility and then its expedition to the processing facility in Petten (Holland). From February 2010 till the end of 2014 were irradiated 1112 uranium plates. Especially important was MARIA reactor operation from the mid of December 2012 till the end of April 2013 when the quantity of delivered for market Mo-99 covered about 15% of global demand. After upgrading of the primary fuel channel cooling system we are available to install an additional channel for U-targets irradiation (increased capacity around 50%). Under collaboration with Mallinckrodt Pharmaceuticals and with reactors HFR and BR-2 we are developing irradiation and transport technology of a new designed LEU targets for molybdenum production.

6.4 Northwest Medical Isotopes, LLC Project Overview and Status

Carolyn Haass
Chief Operating Officer /Vice President
Northwest Medical Isotopes, LLC
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Northwest Medical Isotopes, LLC (NWMI) is designing and constructing a Radioisotope Production Facility (RPF) to produce a domestic, securable, and reliable commercial supply of Mo-99. NWMI has formed a team of U.S. universities and companies to cost-effectively address the need for a domestic Mo-99 supply. NWMI intends to provide approximately 50 percent of the Mo-99 demand in North America and has developed an approach, including manufacturing and processing, using a total LEU solution to be implemented by 2017.

6.5 Towards Domestic Production of Mo99

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NorthStar Medical Technologies, LLC
1800 Gateway Blvd, Beloit, WI 53511 – USA

NorthStar has multiple efforts towards establishing a domestic supply of Mo99. One effort is reactor based utilizing the neutron capture process at the Missouri University Research Reactor (MURR) reactor. The second effort is an electron accelerator based process utilizing the photon capture process at NorthStar's Beloit site. Both processes require a new type of generating system that is capable of accepting a low specific activity solution of Mo99 and yielding a USP

compliant, high specific activity Tc99m product as is currently the case in nuclear pharmacies throughout the US. NorthStar's presentation will describe current status of the neutron capture production process and the FDA status of the RadioGenix™ generating system.

6.6 Niowave's Domestic Production of Mo-99 from Uranium to Start in 2015

Terry L. Grimm, Stephen S. Barnard, Chase H. Boulware, Amanda K. Grimm, Jerry L. Hollister, Mayir Mamtimin, and Valeriia N. Starovoitova
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The lack of a domestic supply of Mo-99 and the current practice of using weapons grade uranium to produce Mo-99 led Congress to pass the American Medical Isotope Production Act in 2013. This legislation establishes a program to develop domestic production of Mo-99 by non-federal entities, and to phase out the use of highly enriched uranium for Mo-99 production. In March 2015 the Nuclear Regulatory Commission approved Niowave's license to produce Mo-99 from low enriched uranium using a superconducting electron linac. The first domestic production of small quantities of Mo-99 will occur toward the end of 2015. Large scale production and distribution of Mo-99 will follow in 2016-17. Chemical processing of the uranium targets will produce Mo-99 of the same quality as the existing supply chain, allowing a smooth transition to a domestic source.

SESSION 7

Regulatory Perspectives

Session Chair: Carolyn Haass

7.1 U.S. Nuclear Regulatory Commission Licensing Activities Related to Molybdenum-99 Production

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Research and Test Reactors Licensing Branch
U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, MD 20852 – USA

This paper provides an update on U.S. Nuclear Regulatory Commission (NRC) licensing activities relating to the establishment of a domestic molybdenum-99 (Mo-99) supply in the United States. Currently, two construction permit applications and one operating license amendment request supporting Mo-99 production are under NRC staff review. In March 2015, the NRC issued a material possession license for small-scale demonstration of superconducting linear accelerator technology. Thorough and timely reviews of current and anticipated license applications are facilitated by public engagement and infrastructure development. Public meetings supplement application reviews, serving as an effective forum for applicants to engage with NRC staff on facility-specific technical and licensing considerations. Ongoing infrastructure

development efforts include the analysis of the NRC's regulatory framework and development of guidance. As applicable, the NRC is coordinating environmental review work with the U.S. Department of Energy and supporting utilization facility site vulnerability assessments conducted by the U.S. Department of Homeland security.

7.2 Impact of High Cost Mo-99 on Healthcare Reimbursement Models

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Centers for Medicare and Medicaid Services
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The end user cost of diagnostic radionuclides are reimbursed through many different mechanisms, both around the world and within the U.S. This talk will present a brief discussion of the manner in which different commercial and government payment systems will respond, at a technical level, to a significant increase in the cost of Mo-99, if such an increase should result from conversion to non-HEU sources, alternate production pathways, FCR, ORC or other factors.

7.3 FDA Activities Promoting Mo-99 Production from non-HEU Processes and Assuring Mo-99 Supply

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Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue WO66-4613, Silver Spring, MD 20993 – USA

7.4 U.S. Nuclear Regulatory Commission Environmental Reviews Related to Molybdenum-99 Production

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This paper describes the U.S. Nuclear Regulatory Commission's (NRC) environmental review of proposed activities relating to the establishment of a domestic molybdenum-99 supply in the United States. The NRC is currently conducting two environmental reviews for construction permits for proposed molybdenum-99 production facilities. In May 2015, the NRC staff published a draft Environmental Impact Statement for SHINE Medical Technologies, Inc.'s construction permit application. The NRC staff is addressing several unique considerations during these first-of-a-kind reviews, such as evaluating the applicability of the NRC's licensing and environmental regulatory frameworks, determining the appropriate level of detail for NRC's

environmental documents, and implementing various methods to ensure efficient and effective reviews for first-time applicants. Future environmental reviews will incorporate lessons learned from the ongoing environmental reviews, including technical considerations, public participation, and coordination with other government agencies and Tribes, as well as other unique site- and project-specific considerations.

SESSION 8

Current and Future Supply Chain Outlook – Session II

Session Chair: Tom Burnett

8.1 Update on LEU TechneLite® Generators

Ira N. Goldman[1], Kathleen Mcfadden[2]
[1]Manufacturing and Operations, [2]Sales and Marketing
Lantheus Medical Imaging
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Lantheus Medical Imaging, Inc. added Technelite® (Technetium $Tc^{99}m$) generator manufactured using Molybdenum-99 (Mo^{99}) produced from low-enriched uranium (LEU) to its product portfolio in January 2013. The LEU Technelite® generator is manufactured in a weekly, dedicated manufacturing run. Centers for Medicare and Medicaid Services (CMS) statements and records indicate that hospitals have been filing for and receiving the $10 add-on payment for non-HEU derived doses that CMS initiated as part of the hospital outpatient prospective payment system (HOPPS) in 2013.

This paper will provide an update regarding supply chain and commercial aspects of LEU Technelite® since the 2014 DOE topical meeting in Washington, including Lantheus' efforts to transition toward an all LEU Mo^{99} supply chain by the end of 2016, dependent upon IRE's conversion to LEU targets planned for mid-2016.

8.2 ANSTO Nuclear Medicine Mo-99 Facility

Michael Druce and Doug Cubbin
Nuclear Business
Australian Nuclear Science and Technology Organisation (ANSTO)
New Illawarra Rd, Lucas Heights, NSW – Australia 2232

ANSTO has in recent years changed its focus from being a domestic producer of radioisotopes to being a supplier to the international market. ANSTO is also focused on being a responsible supplier utilizing only LEU for the production of Mo-99 as well as complying with the guidelines established by the NEA. Construction of a new Mo-99 facility is now well advanced with production to commence in the second half of 2016. The capacity of this facility will be

3500 six day curies per week. An up-date will be given of ANSTO's activities and the status of the new Mo-99 facility.

8.3 Recent Achievements of IRE's LEU Conversion Project

Valery Host
Research and Development Manager
National Institute for Radioelements (IRE), Avenue de l'Esperance, B-6220 Fleurus – Belgium

IRE is actively participating to the reduction of proliferation risks through its commitment to convert radioisotope production lines to the use of LEU targets. Important milestones which confirm the good progress of the project have been recently achieved.

IRE is pursuing the LEU target qualification in various European research reactors to ensure a reliable worldwide supply of medical isotopes. The results of post irradiation examinations and efforts to obtain the LEU transport license are presented.

Major modifications to the entire production chain, from the processing conditions to the production environment, have been achieved to accommodate the new target specifications. Now the LEU conversion program is leaving progressively the development phase to start the practical demonstration of the production operations in the new environment. Process testing with the new safety components as well as Xe-133 recovery for medical use and environmental footprint reduction in cooperation with CTBTO are discussed.

8.4 Considerations Regarding Full Cost Recovery in Direct Production of ^{99m}Tc

K.R. Buckley, V. Hanemaayer, S. McDiarmid, J. Tanguay, M. Vuckovic, M. Dodd,
B. Hook, X. Hou, J. Kumlin, S. Zeisler, A. Celler, M. Kovacs, F.S. Prato, J.F. Valliant,
T. Ruth, F. Bénard, P. Schaffer
The ITAP Consortium, TRIUMF, 4004 Wesbrook Mall, Vancouver BC, V6T 2A3 – Canada

Our consortium has demonstrated reliable commercial-scale (TBq) production of ^{99m}Tc via the (p,2n) reaction on ^{100}Mo-coated tantalum plates at energies up to 24 MeV. Our approach was recently approved by Health Canada to proceed into clinical trial. Efforts to establish a full cost recovery (FCR) process proceed in parallel.

Key considerations for FCR are the costs of the tantalum plates and the enriched molybdenum. In order to limit radioactive waste inventories, and in recognizing the need for specialized target manufacturing equipment, we seek to establish a centralized recycling program. Due to the presence of other minor molybdenum isotopes, and with the interaction of the proton beam with the tantalum plate, there exists Tc, Mo, Nb, W and other radionuclides in the processed target solutions and backing plates. The impact of these various radionuclides on the recycling process will be discussed in the context of overall project progress.

8.5 Next Generation Mo-99 Production: SHINE Update

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SHINE Medical Technologies
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SHINE's advanced isotope production technology combines an accelerator-based neutron source with a high-efficiency liquid target. The target geometry is optimized for isotope production, resulting in high yield of medically-useful products including molybdenum-99 (^{99}Mo), iodine-131, and xenon-133. The SHINE system is more cost-effective and creates less waste than conventional methods, and produces ^{99}Mo compatible with the existing supply chain. Partnerships with National Laboratories have resulted in the production of commercial-purity product, and demonstrated greater-than-anticipated separation and purification yields. In 2014, SHINE signed supply agreements with GE Healthcare and Lantheus Medical Imaging, becoming the only US-based producer or new technology to have executed supply agreements with customers. In May 2015, the NRC issued a draft Environmental Impact Statement for the SHINE facility, concluding SHINE's impact to the environment will be minimal and recommending SHINE be issued a permit to construct. Issuance of the NRC construction permit is expected in Q1 2016.

8.6 Selective Gas Extraction: A Transformational Production Technology being Implemented by GA, MURR and Nordion

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K. Brooks, Missouri University Research Reactor, 1513 Research Park Drive,
Columbia, MO 65211 – USA
C. Critch, Nordion Inc. 447 March Road, Ottawa, Ontario K2K 1X8 – Canada

This collaborative project by GA, MURR, and Nordion utilizes a transformational radioisotope production system to produce the medical isotope Molybdenum-99 (Mo-99) by utilizing existing nuclear infrastructure located in the United States and Canada. The project uses innovative, reusable LEU irradiation targets and integrated gaseous extraction system to generate and selectively remove Mo-99 suitable for use in all existing Tc-99m generators.

The SGE targets will be installed in the MURR reactor reflector region where they receive neutrons from the reactor to produce Mo-99. The targets are designed to allow selective reaction of Mo-99 with a suitable extraction gas during the irradiation process. Mo-99 is mobilized as a gas, which is transferred outside the reactor for collection at MURR and purification at Nordion's existing cGMP facility in Ottawa. This technology does not require the targets to be removed from the reactor and consumed in a conventional sense, and production therefore continues in place for extended periods while generating minimum amounts of radioactive waste. SGE technology maximizes isotope production while minimizing the amount of LEU needed.

The presentation will provide an overview of the GA, MURR, Nordion collaboration, project goals, schedule, and Mo-99 production capacity.

SESSION 9

Poster Session and Reception Fenway Ballroom

MC: Rilla Hamilton

9.1 Removal of Tc from Neutron-Capture ^{99}Mo using Eichrom's ABEC Resin

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Dan De Vries, Dean Beebe and James Harvey
NorthStar Medical Radioisotopes
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NorthStar Medical Radioisotopes is pursuing a neutron capture [^{98}Mo(n,γ)^{99}Mo] route for ^{99}Mo production at the University of Missouri Research Reactor (MURR). Argonne is assisting NorthStar in the development of some aspects of the operation. Once the molybdenum targets are removed from the reactor, they will undergo dissolution. The output of the dissolution results in ~1500 mL of a 200 g/L Mo, 9.3 M K^+, 5 M OH^-, 0.1 M NO_3^- solution containing ~400 Ci of ^{99}Mo, as well as a few byproducts (compared to fission) including Tc. This solution is pumped from a shielded cask through a chromatography column containing ABEC to remove Tc present from the target irradiation. This polishing step will allow radiopharmacies to use the first aliquot of Tc they elute from their generators. Currently, radiopharmacies discard the first aliquot from the generator, as it contains unacceptable levels of ^{99g}Tc. Various ABEC cartridge sizes and flow rates through these cartridges have been investigated, and a method for processing the 1500 mL of 5 M OH^- solution has been investigated.

9.2 Collaborative Efforts between the Medical Isotope Production and the Nuclear Explosion Monitoring Communities

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The Medical Isotope Production (MIP) and nuclear explosion monitoring communities are increasingly aware of challenges created by radioxenon effluents from MIP thanks to meetings such as the fifth Workshop on Signatures of Medical and Industrial Isotope Production (WOSMIP), held in Brussels, May 2015. Radioxenon releases during fission based Mo-99 production are similar to signatures from a nuclear explosion. This similarity is attributable to a

rapid release of encapsulated radioxenon during dissolution of the uranium target shortly after irradiation. Therefore, MIP inadvertently creates a global radioxenon background that can interfere with nuclear explosion monitoring efforts by the Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO). The fifth WOSMIP provided an opportunity for experts from both communities to discuss the radioxenon issue, updates on isotope production methods, technologies used to measure radioxenon (at both MIP facility and monitoring locations), research and development targeted at reducing xenon emissions, and methods for data sharing between the communities.

9.3 Design of High Power Beam Dump and Collimator

R. Gromov, J. Bailey, S. Chemerisov, R. Kmak, V. Makarashvili, G.F. Vandegrift, M. Virgo
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Argonne National Laboratory, 9700 S. Cass Avenue, Argonne, IL 60439 – USA

Argonne is funded by the National Nuclear Security Administration's (NNSA) Office of Material Management and Minimization (M^3) to assist NorthStar Medical Technologies to develop an electron-accelerator-based system that produces ^{99}Mo by a γ,n reaction on a ^{100}Mo target. This production facility will require a high-energy beam dump system and a collimator to provide safe beam tuning and delivery to the production area. The projected beam parameters are as follows: energy 40-42 MeV, average power 120 kW, repetition rate 800 Hz. The beam collimator is to be installed before the target to protect the target holder and the surrounding area from excessive power deposition from the beam. The beam dump is to be used like a beam stop for tuning the accelerator for nominal power and beam shape before putting it directly on the target. For these purposes we designed a system that combines a water-cooled set of aluminum plates with ribs. To minimize the thermal stress, two separate water loops were used. The beam collimator is composed of a water-cooled aluminum cylinder. It is electrically insulated from the vacuum chamber by ceramic holders.

9.4 UAlx Phase Analysis on the LEU Dispersion Targets with Changing the Composition of Atomized UAlx Powders

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KAERI has been developing the LEU dispersion target for its supply to new research reactor which will be constructed at Kijang site in Korea. For LEU dispersion target, we fabricated two kinds of atomized UAlx powders having different contents of UAl2 and UAl3 phase. With using these two kinds of atomized UAlx powders, dispersion targets having an uranium loading of 2.6gU/cc were fabricated and inspected. In order to convert UAl2 phase to UAl3 phase for Mo-99 extraction, heat-treatments were conducted to two kinds of dispersion targets. In this paper, we investigate the optimal condition of heat-treatment by using XRD analysis.

9.5 Update on IAEA Activities Supporting Non-HEU Production of Mo-99 & Tc-99m

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Technetium-99m (^{99m}Tc) is the most employed medical radioisotope, amounting to about 30 million studies per year and accounting for more than 80% of all procedures in diagnostic nuclear medicine. ^{99m}Tc is obtained from its parent nuclide molybdenum-99 (^{99}Mo), an isotope that is most commonly produced through the fission of uranium targets in research reactors. Since 2008, the supply chain for this strategic radioisotope has experienced shortages due to unexpected shutdowns both at reactors and processing facilities. The possibility of future shortages remain, particularly as some of the key reactors producing ^{99}Mo cease operation, either permanently or for prolonged periods for maintenance and facility upgrades.

Realizing the need to support Member States in mitigating the effects of a supply crisis of ^{99}Mo/^{99m}Tc in the future, the IAEA facilitates a number of activities that will be highlighted in this paper. The following IAEA activities will be presented: (i) the Mo-99 HEU minimization project, aimed at the transition of ^{99}Mo production away from the use of HEU, (ii) the Coordinated Research Project on "Accelerator-based Alternatives to Non-HEU Production of Mo-99/Tc-99m", aimed at the direct production of ^{99m}Tc through the reaction ^{100}Mo(p,2n)^{99m}Tc using cyclotrons, (iii) the Peaceful Uses Initiative project on "Supporting the Global Deployment of Mo-99 Production Capacity for Nuclear Medicine Applications without the Use of Highly Enriched Uranium (HEU)", aimed at assisting small-scale, national-level producers in setting up their production capability using low enriched uranium (LEU) fission or the ^{98}Mo(n,γ)^{99}Mo reaction, (iv) the new Coordinated Research Project on "Sharing and Developing Protocols to Further Minimize Radioactive Gaseous Releases to the Environment in the Manufacture of Medical Radioisotopes, as Good Manufacturing Practice", aimed at mitigating emissions from medical isotope production, and (v) a Round Robin exercise aimed at providing experimental results on production capabilities of the participating research reactors of ^{99}Mo based on ^{nat}Mo(n,γ)^{99}Mo reaction for supply to local users. The outcomes of these projects thus far as well as the activities planned for the future will be discussed.

9.6 Development of Atomized UAl_x Powder for Mo-99 Target Fabrication

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Research Reactor Fuel Technology Development Division
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Uranium metal dispersion particle has been proposed as targets for Mo-99 production to improve the radioisotope production efficiency of conventional low enriched uranium targets. In this study, the manufacturing process for atomized UAl_x powder was improved using a UAl_x mother alloy. Atomization without the UAl_x mother alloy resulted in leakage of the molten metal due to severe thermal shock during mixing of U and Al. It is considered that a step to cast a UAl_x mother alloy is needed to achieve stable fabrication for atomized UAl_x powder. The shape and morphology of the atomized UAl_x powder were examined with a scanning electron microscope (SEM) equipped with an energy dispersive spectrometer (EDS) and the phase constitution of the powder was determined by means of X-ray diffractometry.

9.7 Scalability of the LEU-Modified Cintichem Process

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Argonne National Laboratory with the National Nuclear Security Admiration's (NNSA) Material Minimization and Management program (M^3), in partnership with SHINE Medical Technologies are developing technologies for the domestic production of ^{99}Mo. SHINE is planning to produce ^{99}Mo by fission of low enriched uranium (LEU) in a subcritical aqueous solution using accelerator-based neutron generation. In support of this goal, irradiations at Argonne's Van-de- Graaff facility simulating LINAC irradiations were performed. The LEU- Modified Cintichem process has been chosen by SHINE to process their irradiated solutions. However, Cintichem rarely processed more than 1000 Ci of ^{99}Mo in a single batch. A concern is the Mo-ABO complex will break down under high dose conditions, causing a decrease in the recovery of ^{99}Mo. Irradiations of the Mo-ABO solid have been performed and the results will be discussed.

9.8 Robust Medical Isotope Production System

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A concept design for a medical isotope production system employing fissile solution fuel has been developed which would provide sufficient quantities of Mo-99 to meet national needs. Development and operational costs are consistent with a full cost recovery business model. The design is meets export control and non-proliferation objectives to provide accessibility to regional facilities in developing countries world-wide. The design is based on proven technology, utilizes readily procured hardware and avoids the need for a supply chain of uranium targets as is required by traditional reactor based systems. It represents a relatively low cost, low risk technology to produce large quantities of important radioisotopes.

9.9 Generation of Gas Bubbles in a Fissioning Uranyl Sulfate Solution Using an Electron Beam Linac

T.A. Heltemes, S.D. Chemerisov, R. Gromov, V. Makarashvili, Z. Sun, K.E. Wardle, J.L. Bailey, D.C. Stepinski, J.L. Jerden, M. Basavarajappa, and G.F. Vandegrift
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In support of the development of accelerator-driven production of fission product Mo-99 as proposed by SHINE Medical Technologies, a 35 MeV electron linac was used to irradiate depleted-uranium (DU) uranyl sulfate dissolved in pH 1 sulfuric acid at average power densities of 6 kW, 12 kW, and 15 kW. During these irradiations, gas bubbles were generated in solution due to the radiolytic decomposition of water molecules in the solution. Multiple video cameras were used to record the behavior of bubble generation and transport in the solution. Seven six-channel thermocouples were used to record temperature gradients in the solution from self-heating. Measurements of hydrogen and oxygen concentrations in a helium sweep gas were recorded by a gas chromatograph to estimate production rates during irradiation. These data are being used to validate a computational fluid dynamics (CFD) model of the experiment that includes multiphase flow and a custom bubble injection model for the solution region.

9.10 Design of a Tritium Purification Process for SHINE™ Mo-99 Production

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SHINE™ Medical Technologies has developed a Subcritical Hybrid Intense Neutron emitter (SHINE) to create molybdenum-99 (Mo-99) via fission of uranium-235 (U-235) in a subcritical aqueous phase solution. An accelerator-based neutron generator, developed by Phoenix Nuclear Labs, creates D-T neutrons for irradiation of U-235 bearing solutions. As part of accelerator operations, the tritium used for neutron production will be recovered, undergo impurity removal and isotopic separation before being reused for accelerator operations.

This paper discusses the efforts of Savannah River National Laboratory (SRNL) to assist SHINE™ Medical Technologies in the design of a Tritium Purification System (TPS). In addition to supplying a process-critical technology for isotope separation (TCAP), SRNL aided in the design of the TPS, the glovebox confinement systems, and glovebox stripper system (GBSSs) for the TPS. The TPS is a novel, low inventory, continuously operating tritium process system.

9.11 Experience of LEU Mo-99 Production with the MINI-LOOP System

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MIPS Project
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INVAP designed a system named MINI-LOOP for the development and testing of a process for separation and purification of Mo-99 obtained by fission of low enriched uranium solutions. The MINI-LOOP is conformed principally by the irradiation and processing systems. The program was performed in less than 3 years, during that time the following work was done:

- Design basis definition
- Constructive design
- Fabrication
- Assembly and installation
- Commissioning
- Operation and maintenance
- Waste management
- Re design and adjustments
- Observations and results analysis

As the result of the overall program a new method for the production of Mo-99 was defined. Actually the system is under a decommissioning program.

SESSION 10

Technology Development – Session I

Session Chair: Chris Bryan

10.1 SHINE Chemistry Overview

A.J. Youker, J. Byrnes, S. Chemerisov, R. Gromov, A. Hebden, T. Heltemes, J. Jerden, C. Jonah, M. Kalensky, J. Krebs, V. Makarashvili, K. Quigley, D. Rotsch, D. Stepinski, P. Tkac, G.F. Vandegrift
Nuclear Engineering Division
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As part of the Material Management and Minimization (M^3) Mo-99 Technology Development program, Argonne is helping to accelerate the domestic production of Mo-99. Today's presentation will focus on the work being done at Argonne to support SHINE Medical Technologies in their efforts to produce fission-product Mo-99 via an accelerator-driven process. Argonne's mini-SHINE experiments will produce 2 Ci (phase 1) and 20 Ci (phase 2) of Mo-99 for shipment to SHINE's potential Tc-99m generator manufacturer partners.Mo-99 will be

produced using a low-enriched uranium (LEU) uranyl-sulfate target solution, an electron linac, and a tantalum (phase 1) or depleted-uranium target (phase 2) for neutron production. Results from the phase 1 mini-SHINE experiments show a delay in oxygen generation, indicate no change in Mo oxidation state, and prove that the final Mo-99 product does meet required purity specifications. Once the Mo-99 product is shipped to GE Healthcare, phase 1 equipment will be removed and phase 2 will be installed.

10.2 PVD-based Manufacturing Process of Monolithic LEU Foil Targets for ^{99}Mo Production

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The complete fabrication of the cylindrical LEU foil target was demonstrated using a newly developed manufacturing method. Hereby, the uranium as well as the interlayer material is coated directly on the inside of the outer cladding cylinder. This process was realized by a cylindrical magnetron enhanced PVD technique (sputtering). The set-up was extensively parametrized and an algorithm was developed, which allows the calculation of the grown layer thickness in real time or to simulate different sputter procedures. By adjusting the process parameters, the mechanical properties of the produced foils, their thickness homogeneity and the material utilization were optimized. In this way, self-supporting uranium foils with a good mechanical strength and a high thickness homogeneity were produced. By the application of a suitable interlayer material, these uranium foils were easily separable from the aluminum cladding. The material utilization of the uranium sputter process was above 90%.

10.3 Engineering and Design Activities at Los Alamos National Laboratory Supporting Commercial U.S. Production of ^{99}Mo without the Use of HEU

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Los Alamos National Laboratory (LANL) is supporting the commercial U.S. production of ^{99}Mo as part of the National Nuclear Security Administration (NNSA) office of Materials Minimization and Management (M^3) program to accelerate the establishment of a reliable domestic supply of ^{99}Mo without the use of highly enriched uranium (HEU). In partnership with several other national laboratories, we are currently providing engineering design and support to NorthStar Medical Radioisotopes and SHINE Medical Technologies. The NorthStar technology uses an electron beam from an electron accelerator incident on enriched ^{100}Mo targets to produce ^{99}Mo through the (γ,n) photonuclear reaction. The SHINE technology uses a subcritical

accelerator-driven uranium solution to produce fission product ^{99}Mo. LANL personnel are providing engineering and design support to both of these companies as part of the M^3 program. This presentation will give an overview of the two technologies, our support activities, and recent experimental results.

10.4 Feasibility of Transmutational Production and Magnetic Extraction of Moly-99 via 1-neutron Knockout and Exchange Reactions in Auto-colliding Beam of Natural Mo Ions in Strong-focusing Precetron ("EXYDER") and Electric Energy Recuperation by Ion Decelerator

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Copious T and ^{3}He production in auto-colliding 0.725 MeV D+ beam of Precetron (MIGMA IV), has opened novel transmutational isotope manufacture. We propose a feasibility study for an upgraded Precetron ("EXYDER'') by replacing weak with strong focusing to manufacture ^{99}Mo via n- exchange ^{100}Mo + ^{98}Mo→2 ^{99}Mo and n- knockout reaction ^{100}Mo + ^{x}Mo→^{99}Mo + ^{x}Mo+n, x = 94-98 (natural isotopes). From EBIS Preinjector 17 times ionized beam of ^{x}Mo^{17+} of will be accelerated by 3 MeV injector to 50 MeV thus resulting in 50 MeV→←50 MeV collisions. Beam of so produced ^{99}Mo^{+} is magnetically channeled into mass spectrometer and collected at one loci, all other masses/radii rejected. Parameters required to produce at 8 to 80 mg of ^{99}Mo per day will be presented.

10.5 Corrosion Assessment of Candidate Materials for the SHINE Subcritical Assembly Vessel and Components

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Laboratory corrosion testing of candidate alloys—including Zr-4 and Zr-2.5Nb representing the target solution vessel, and 316L, 2304, 304L, and 17-4 PH stainless steels representing process piping and balance-of-plant components—is underway in support of the proposed SHINE process to produce ^{99}Mo from low-enriched uranium. The testing utilizes depleted uranyl sulfate in various concentrations and incorporates a range of temperatures, excess sulfuric acid concentrations, and iodine additions. Testing has included static immersion of coupons (fully immersed and in vapor), galvanic tests featuring couples between a stainless steel and a zirconium-based alloy, U-bends (fully immersed and in vapor), slow-strain rate exposures, and electrochemical polarization as a function of rotating disk speed. Preliminary testing has also included encapsulated exposures in a spent fuel pool to generate active gamma-radiolysis

conditions. Results to date indicate the candidate alloys are quite resistant to general and localized corrosion under a wide range of exposure conditions.

SESSION 11

Technology Development – Session II

Session Chair: Thad Heltemes

11.1 Development of Accelerator Based Production of Mo-99

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The National Nuclear Security Administration's (NNSA) Office of Materials Management and Minimization, in partnership with commercial entities and the US national laboratories, is working to accelerate the establishment of a reliable domestic supply of Mo-99 for nuclear medicine while also minimizing the civilian use of HEU. Argonne National Laboratory (Argonne) is supporting NorthStar Medical Radioisotopes LLC and SHINE Medical Technologies in their efforts to become domestic Mo-99 producers. NorthStar Medical Radioisotopes, LLC is utilizing the photonuclear reaction in an enriched Mo-100 target for the production of Mo-99. In this approach a high-power electron accelerator is used to produce the required flux of high-energy photons through the bremsstrahlung process. Argonne is assisting in developing the irradiation system, target processing, and enriched-Mo recycle. SHINE Medical Technologies is developing SHINE, a system for producing fission-product ^{99}Mo using a D/T-accelerator to produce fission in a non-critical target solution of aqueous uranyl sulfate. Argonne is assisting SHINE in development Mo-99 separation and purification systems using mini-SHINE experimental setup. In this presentation we will review accelerator related aspects of the project.

11.2 Powder Metallurgy Fabrication of Molybdenum Target Materials and Assemblies

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Powder metallurgy approaches for the fabrication of accelerator target materials are being examined to support the development of Mo-99 production by NorthStar Medical Technologies, LLC. An advantage of powder metallurgy is that very little material is wasted and at present,

dense, quality parts are routinely produced from molybdenum powder. The current target design is a thin wafer, 29 mm in diameter with a thickness of 0.5 mm, with very stringent dimensional tolerances. Combinations of powder morphology, lubricants, pressing technique and sintering conditions have been explored to produce target disks with minimal variations in thickness and little or no distortion. Thermomechanical and thermophysical properties as well as thermal stability are being examined to support target design and assess in-accelerator material performance. In addition to the typical "press and sinter" approach to the fabrication of targets, additive manufacturing is being explored to produce complete target assemblies. This effort includes development of spherical powders for feedstock and characterization of processing-microstructure-property relationships to support design and modeling of performance.

11.3 ^{100}Mo to ^{99}Mo Production Target: Design Status and Test Results

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The NorthStar Medical Technologies ^{99}Mo production scheme utilizes a 42 MeV electron beam on a ^{100}Mo target comprised of a stack of thin disks cooled with helium through narrow gaps between the disks. With 2.86 mA beam current on each end of the target, the total heat load is 154 kW (64% of the beam power) and the peak heat flux is nearly 1500 W/cm^2. Ongoing design and analysis studies to optimize performance are reported, as well as results from flow testing at LANL and an in-beam thermal test at ANL. Current design activities are focused on reducing the number of disks by grading the thickness as a function of depth into the target and optimizing the coolant gap width for optimal use of the new, larger blower configuration. Also reported are the description and performance measurements of the new blower now operational at LANL.

11.4 Chemical Processing Activities for ^{99}Mo Production by (γ,n) and (n,γ) Reactions using Enriched ^{100}Mo and ^{98}Mo Targets

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Recently, several technologies were proposed for the production of ^{99}Mo/^{99m}Tc without use of ^{235}U targets. These technologies offer the potential for a lower-cost alternative to fission produced ^{99}Mo, but with lower yields of ^{99}Mo or ^{99m}Tc. Enriched ^{98}Mo or ^{100}Mo targets are necessary for economic production of several thousand Ci of ^{99}Mo. Argonne, in collaboration with Los Alamos and Oak Ridge National Laboratories, are assisting NorthStar Medical Technologies in the development of domestic supply of ^{99}Mo. NorthStar's short-term plan is to produce ^{99}Mo using ^{98}Mo(n,γ)^{99}Mo reaction at MURR, and their long-term solution is to produce ^{99}Mo using an electron accelerator accelerators via the ^{100}Mo(γ,n)^{99}Mo reaction. The latest

experimental results from irradiation of enriched ^{100}Mo targets, large-scale dissolution studies, and development of enriched material recycle process will be presented.

11.5 Neutron Irradiation Testing of Structural Components in Support of an Accelerator Driven Subcritical Assembly for the Production of Mo-99

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The SHINE Medical Technologies subcritical hybrid fusion-fission device for the production of medical and diagnostic isotopes offers unique materials challenges that include environmental contact with uranyl sulfate solutions and a relatively intense radiation environment. Zircaloy-4 has been used extensively in chemically challenging and high radiation environments and has been selected as the primary structural material for the assembly based on its exceptional historic behavior under irradiation and corrosion tolerance. However, much of the irradiation and corrosion database available is for power reactor applications with conditions not necessarily observed in the SHINE assembly.

Our work outlines these environmental factors, the materials selection of the structural components involved in the target solution vessel (TSV) and periphery components and the developed test plan being implemented to evaluate the structural materials for a 30- year operation. Comparative work between alpha-annealed and beta-quenched forms of Zircaloy-4 and a Zr-2.5Nb alloy have been examined in the as-fabricated form, similar metal electron-beam and tungsten inert gas welds, and hydrogen charged conditions both before and after neutron irradiation exposure through mechanical property and microstructural characterizations. Testing has also involved 316L stainless steel, the primary material for support components to the TSV, and a duplex (ferritic/austenitic) 2304 grade steel as a potential candidate for consideration. This report will summarize the results to date of this testing.