

**RERTR 2010 – 32nd INTERNATIONAL MEETING ON
REDUCED ENRICHMENT FOR RESEARCH AND TEST REACTORS**

**October 10-14, 2010
SANA Lisboa Hotel
Lisbon, Portugal**

**IAEA ACTIVITIES TO SUPPORT THE TRANSITION OF
MOLYBDENUM-99 PRODUCTION AWAY FROM THE USE OF
HIGHLY ENRICHED URANIUM**

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ABSTRACT

With the financial support of the US DOE/NNSA, the Government of Norway and the Nuclear Threat Initiative, the IAEA has been and remains an active partner in international efforts to reduce or eliminate the use of highly enriched uranium (HEU) from civilian, nuclear endeavors. Since 2005, an ongoing Coordinated Research Project (CRP) on Developing Techniques for Small Scale Indigenous Mo-99 Production Using Low Enriched Uranium (LEU) Fission or Neutron Activation has been making significant progress and supporting projects in several Member States. In parallel with this CRP, a number of IAEA fostered Research Reactor Coalitions have formed with objectives that include Mo-99 production without the use of HEU. Work that commenced in 2007 has evolved into another CRP on the Feasibility Evaluation of the Use of Low Enriched Uranium Fuelled Homogeneous Aqueous Solution Nuclear Reactors for the Production of Short Lived Fission Product Isotopes. The IAEA is also supporting the OECD/NEA-organized High Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) as an observer. During 2010, work was begun to develop a comprehensive document on the status and prospects of various non-HEU Mo-99 production technologies. Finally, an International Working Group was launched by the IAEA in August 2010 to provide support to HEU to LEU conversion projects underway or being considered by current, major Mo-99 producers. This paper provides additional detail and updates of the aforementioned activities.

1. Introduction

Technetium 99m (Tc-99m), the daughter product of Molybdenum 99 (Mo-99), is the most commonly utilized medical radioisotope in the world, used for well over 30 million medical diagnostic procedures annually and comprising some 80% of all diagnostic nuclear medicine procedures. Until 2010, approximately 95% of Mo-99 consumed worldwide has been produced in research, test or isotope production reactors by the irradiation of Highly Enriched Uranium (HEU) targets that are subsequently processed primarily to recover Mo-99. There are mainly four large-scale commercial processors of Mo-99 (i.e. 1000 6-day curie or more per week), three of them utilize HEU targets and dedicated processing facilities, while a fourth, (NTP/SAFARI-1, South Africa) is converting its process to Low Enriched Uranium (LEU) and a fifth producer (ANSTO Health/OPAL, Australia) is expanding current LEU-based production.

The Minimization of Highly Enriched Uranium (HEU) in the Civilian Nuclear Sector Symposium, Oslo, Norway, 17-20 June, 2006 suggested, “The production of medical and other isotopes using LEU targets should to the extent possible be encouraged, taking into account technical and economic considerations” [1]. The Global Initiative to Combat Nuclear Terrorism, Workshop on the Production of Mo-99 Using Low Enriched Uranium, held in Sydney, Australia, 2-5 December 2007 [2], and the U.S. National Academy of Science 2009 study (NAS study) *Medical Isotope Production without Highly Enriched Uranium* [3] both concluded that production of Mo-99 from LEU targets has been technically demonstrated, and that any new Mo-99 production facilities should be based on LEU. They also stated that the conversion of existing Mo-99 facilities is technically feasible, although certain technical and financial/economic issues will have to be addressed. The NAS study also concluded that “LEU targets that could be used for large-scale production of Mo-99 have been developed and demonstrated” and “...the committee sees no technical reasons that adequate quantities cannot be produced from LEU targets in the future.” Furthermore, during the April 2010 Nuclear Security Summit [4], Participating States agreed to collaborate “... to research and develop new technologies that require neither highly enriched uranium fuels for reactor operation nor highly enriched uranium targets for producing medical or other isotopes, and will encourage the use of low enriched uranium and other proliferation-resistant technologies and fuels in various commercial applications such as isotope production;” and “...will provide assistance to those States requesting assistance to secure, account for, consolidate, and convert nuclear materials”.

In line with the international objective of minimizing and eventually eliminating the use of HEU in civil commerce, national and international efforts have been underway to transition Mo-99 production away from HEU targets. A small but growing amount of the current global Mo-99 production is derived from the irradiation of LEU targets or the activation of Mo-98. CNEA Argentina successfully converted its small-scale Mo-99 production to LEU and has been routinely producing for several years. BATAN, Indonesia is converting Mo-99 production to LEU, based on foil targets and the LEU-Modified Cintichem process with assistance from Argonne National Laboratory, USA. New LEU-based Mo-99 commercial-scale production facilities have been constructed by INVAP, S.A. (Argentina) based on CNEA targets and processing methods at ANSTO (mentioned above) and at the ETRR-2 research reactor in Egypt (currently in commissioning phase). India and China produce neutron activation based Mo-99 for domestic use in gel generators, while Kazakhstan operates a centralized gel generator facility

with activation based Mo-99 for distribution of Tc-99m in Almaty. Kazakhstan is expected to also supply portable gel generators for its domestic market in the near future. Finally, Gamma Services Group (GSG) is actively marketing Mo-99 chemical processing technologies as being fully compatible with the use of LEU targets.

In view of the supply crisis situation prevailing since the end of 2007, international efforts focused on options to address isotope supply reliability. Major ongoing repairs were completed during the third quarter 2010 at two reactors, easing the immediate supply concerns. Following their return to service, a shift in focus back to long-term sustainability aspects, including the transition away from HEU, is necessary [5].

2. Coordinated Research Project on Developing Techniques for Small Scale Indigenous Mo-99 Production Using Low Enriched Uranium (LEU) Fission or Neutron Activation

The Coordinated Research Project (CRP) on Developing Techniques for Small Scale Indigenous Mo-99 Production Using Low Enriched Uranium (LEU) Fission or Neutron Activation was initiated in 2005 to support the development of local production knowhow. Currently, 8 agreement holders and 6 contract holders are either developing local production capability or supporting the development work of others.

In Chile, fission based production, using an LEU foil target and the modified Cintichem process was anticipated to begin in 2010, but was deferred to 2011 when resources were diverted to support national relief efforts from the February 2010 earthquake. However, the Chilean project counterpart organization – CCHEN, will host a November Workshop on Mo-99 Waste and Quality Management.

In Kazakhstan, INP completed all technical work related to portable gel generators for use in hospitals and nuclear medicine centers and is currently in the third phase of clinical trials. The completion of this phase is expected by December 2010; after which INP will supply such gel generators for Kazakhstan's national Mo-99 needs via neutron activation based production. The total facility capacity is roughly 200 6-day curies. The CRP-supported collaborative interaction between India and Kazakhstan is a notable feature in this development.

IPEN-CNEN/SP in Brazil joined the CRP in late 2009 as an agreement holder. Taking advantage of existing, domestic facilities and capabilities, a program to develop LEU fission Mo-99 capacity is underway. Preliminary experiments have been completed to consider an LEU alkaline process as well as modified Cintichem technology.

In July 2010, PINSTECH initiated hot commissioning of a turnkey process purchased from GSG – formerly ITD – of Germany. Commissioning work involved the irradiation and processing of a single, HEU target plate. The observed, final yield was 69.6%. Parallel development work on an LEU target is progressing. Powder metallurgy experiments have been completed. Neutronic and thermohydraulic calculations are in progress to support future LEU target irradiations. In parallel, activation based Mo-99 is being produced for R&D purposes, but not being used on medical patients.

In Egypt, the AEA has purchased a turnkey facility from INVAP. Installation and cold commissioning of the facility are complete and hot commissioning is to begin on the 4th quarter 2010 with a short-term production goal of two batches of ~100 6-day curies per week using LEU UAl dispersion targets. In support of this project and at the invitation of the Egyptian Government, the IAEA led two technical missions to Egypt to assess reactor safety, the status of Mo-99 production capability (reactor and processing), as well as the organizations readiness to enter the Mo-99 supply market. The missions were completed in July and August. Reports from experts have been received and reviewed by the IAEA. Their input will be combined into a formal reply to the requesting organization. . The IAEA will continue to encourage and support the EAEA in early commencement of regular production and exploring regional supplies.

Efforts by POLATOM in Poland are at an advanced stage of development and investment is being sought for infrastructure upgrades necessary to deploy the production technology. Similarly in Romania, INR has completed development work on target manufacture and completed processing experiments. Medium scale production (~ 700 6-day curies per week) could begin in late 2010 or early 2011. INR is also considering the necessary infrastructure upgrades that will facilitate increased production (>3,000 6-day curies per week) based on the fission of LEU metal foil targets and Mo-99 recovery via the modified Cintichem process. Meanwhile, Tajoura staff in Libya have received equipment throughout 2010 – including a target opener from the University of Missouri – and are planning to conduct processing trials in December with direct assistance from CRP Agreement holders Argonne National Laboratory (ANL) and the University of Missouri.

Following the completion of the CRP, ongoing IAEA support will transition from development to non-HEU technology deployment activities. A variety of IAEA mechanisms may be utilized from 2011 to provide this support. As an example, a concept for an Inter-regional technical cooperation project to directly support the deployment of non-HEU, fission-based, Mo-99 production technologies is currently under review.

3. Research Reactor Coalitions working to produce non-HEU Mo-99

The Eurasia Consortium was formally launched in November 2008 at the IAEA headquarters in Vienna. The coalition has the capabilities and expertise of the nuclear research institutes in the Czech Republic, Hungary, Kazakhstan, Ukraine and Uzbekistan, and cGMP certified isotope processing capabilities of the Institute of Isotopes in Hungary. In December 2009, the coalition shipped a sample of Mo-99 to the USA for quality testing and received positive results. Work toward full FDA approval continues and is expected.

The coalition is seeking funding partners to assist with site specific equipment for irradiation and processing, resolution of transport logistics, procurement of enriched Mo-98, pilot scale Mo-98 enrichment demonstrations using alternate technologies, confirmation of process issues for low specific activity Mo-99, and to complete FDA and other regulatory approval.

The IAEA has assisted the Eurasia Consortium, as well as other research reactor coalition initiatives, by bringing the various parties together and helped forge the network and providing

technical and management expertise. Future, ongoing assistance will focus on technology demonstration and the resolution of logistics issues. [6]

4. Coordinated Research Project on Feasibility Evaluation of the Use of Low Enriched Uranium Fuelled Homogeneous Aqueous Solution Nuclear Reactors for the Production of Short Lived Fission Product Isotopes

In 2007, the IAEA convened a group of experts to review the status of homogeneous, solution reactor technology for the production of medical isotopes. Their report identified a number of opportunities and challenges [7]. It also included a number of recommendations that formed the basis for a CRP on Feasibility Evaluation of the Use of Low Enriched Uranium Fuelled Homogeneous Aqueous Solution Nuclear Reactors for the Production of Short Lived Fission Product Isotopes. The CRP was initiated in 2009 and held its first Research Coordination Meeting (RCM) in February 2010 [8].

Currently the CRP has three contract holders in China, Pakistan and the Russian Federation and one agreement holder from Japan. Independent experts from France and Germany participated in the first RCM and representatives from B&W, Covidien, the US NRC and the US DOE/NNSA attended as observers. Work focused on the challenges related to steady state solution reactor operation, computer modeling and simulation, long term fission product buildup, waste management, and challenges related to satisfying pharmacopeia requirements. Research workplans were developed. Progress and actions will be reported during a second RCM in 2011.

5. Report - Current and Novel, Non-HEU based Isotope Production and Supply Technologies for Mo-99 and Tc-99m suitable for Medical Procedures

The IAEA has participated in the HLG-MR as an observer since the group's inception. Through this participation, the IAEA has contributed to HLG-MR efforts to address global Mo-99 supply security issues in the short-term and global Mo-99 market challenges over the medium- to long-term [9].

An expected output from the HLG-MR is an economic review of potential Mo-99 / Tc-99m production technologies. The report will include HEU based production since the technology is fully deployed and serves as an economic baseline for comparison with other technologies.

In parallel, the IAEA launched an activity in March 2010 to complete a technical readiness review of potential non-HEU based Mo-99 / Tc-99m production technologies. The purpose of this review is to gather evidence of production technology deployments, demonstrations, and/or related experiments to permit the objective assessment of technology and manufacturing readiness levels. During the March meeting, international experts developed an activity workplan, a list of technology holders and relevant contacts, and divided the activity scope into four technology areas: reactor fission, reactor non-fission, accelerator non-fission and accelerator fission. A related area on generator technology – in particular for low specific activity Mo-99 – was also included.

Work progressed through late June to compile inputs on the status of various technologies via voluntary survey submittals. To date 32 submissions have been received and work is in progress to complete the first draft of the report before the end of 2010. A follow-up meeting to review and finalize the draft is being organized for February 2011 with an aim to publish the report later that year. This report is expected to supersede a 1999 IAEA-TECDOC: *TECDOC-1065 – Production Technologies for Mo-99 and Tc-99m* [10].

6. International Working Group - Conversion Planning for Mo-99 Production Facilities from HEU to LEU

As part of the IAEA's continuing involvement to address the medium- to long-term threats to Mo-99 supplies, including in cooperation with the HLG-MR, the IAEA convened an August 2010 Consultancy to identify and help develop a plan to address the technical and related issues associated with the conversion of existing isotope production facilities to LEU-based production. The major technical concerns associated with conversion are: (1) a target design that will allow five-times more uranium in the same geometry as the current HEU target (therefore require no additional irradiation positions in the reactor and no additional targets to be processed), and (2) integrating this new target into current HEU-based processes with minimal modification to the process with the same or higher yield and purity as current target and process combinations. Means to lower liquid and gaseous radioactive-waste generation were also considered. The meeting established a nominal "roadmap" of the activities that need to be carried out in order to accomplish such conversions, as a basis for further activities, and defined related schedule and cost-related issues. The January 2009 NAS study, the work of the HLG-MR, and parallel IAEA activities were important sources of relevant background information.

Three (Covidien, IRE, and NTP) of the four current, major producers participated in the meeting. NTP reported the advanced progress of phase one (of two) of their conversion project. A representative from a future Mo-99 producer at NIIAR (Russia) reported progress on a project that will produce Mo-99 via HEU target irradiation, possibly prior to the end of 2010. Other participants included representatives of CNEA (Argentina), ANSTO (Australia), FRM-II (Germany), the Gamma Services Group (GSG) – formerly ITD – (Germany), Dr. A. A. Sameh (independent expert - Germany), BATAN (Indonesia), KAERI (Korea), INR (Romania), the University of Missouri (USA), the ANL (USA), B&W/Y-12 (USA) and the DOE/NNSA (USA).

An output of this Consultancy was the formation of an International Working Group (IWG) on Conversion Planning for Mo-99 Production Facilities from HEU to LEU [11]. Areas of collaborative work include high density, LEU Mo-99 target development (uranium density $\geq 6\text{g/cm}^3$); closely related front-end adaptive processing technologies; and back-end technology and options assessments – including opportunities for the recovery and recycling of low burnup, LEU.

The University of Missouri, B&W/Y12, ANL and INR (Romania) presented work to develop a detailed safety case for an LEU, metal, foil target. The aim is to complete a testing program at the INR TRIGA reactor and then develop a generic safety case to be distributed as open source information.

Work related to the use of U_3Si_2 targets in Karlsruhe, Germany, including the successful implementation of front-end, adaptive processing technology and a back-end uranium recovery and recycling program was also discussed. Detailed information related to this closed, Mo-99 production cycle has been received by the IAEA and will be made available via the IAEA website.

Finally, waste management strategies and technologies were discussed. Information on SYNROC, a technology developed in Australia and potentially useful for the permanent immobilization of active waste, was shared with the IWG.

The ongoing scope of the IWG is to support the development of target, front-end processing and back-end technologies for consideration by the producers. Producers would then complete individual / custom adjustments to accommodate the unique needs of the different production technologies while maintaining the confidentiality of existing, processing technology.

7. Conclusion

The need to ensure sustainable, reliable and secure Mo-99 supply to patients worldwide has been underscored repeatedly over the past several years. Coordinated, international efforts to address market, technology, and policy issues are likely in the near- and medium-term with equally likely resultant changes to the current Mo-99 supply chain [12]. Through numerous, available mechanisms and with ongoing, international support, the IAEA has accelerated its efforts to facilitate a transition away from HEU based Mo-99 production. Support will continue to be provided to current and future small- and large-scale producers; reactor, non-reactor and processing facilities; and currently deployed as well as novel technologies. Thus the IAEA will help ensure a transition away from HEU based production occurs as part of a shift toward a more secure global supply chain.

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