



60 Years

IAEA

Atoms for Peace and Development

Technical Aspects of Non-HEU Mo-99 & Tc-99m Production: An IAEA Update

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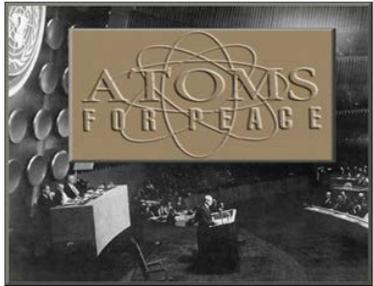
International Atomic Energy Agency

Mo-99 Topical Meeting
10-14 September 2017 Montreal

International Atomic Energy Agency (IAEA)



1953 : UN General Assembly
1957 : IAEA born-Vienna; 56 MS
2005 : Nobel Peace Prize
2016 : 168 MS; ~ 2500 staff



Statutory Mandate

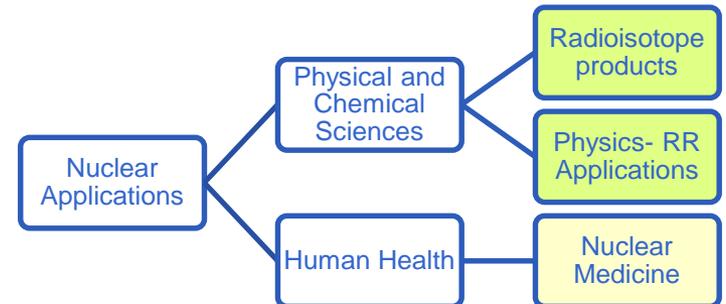
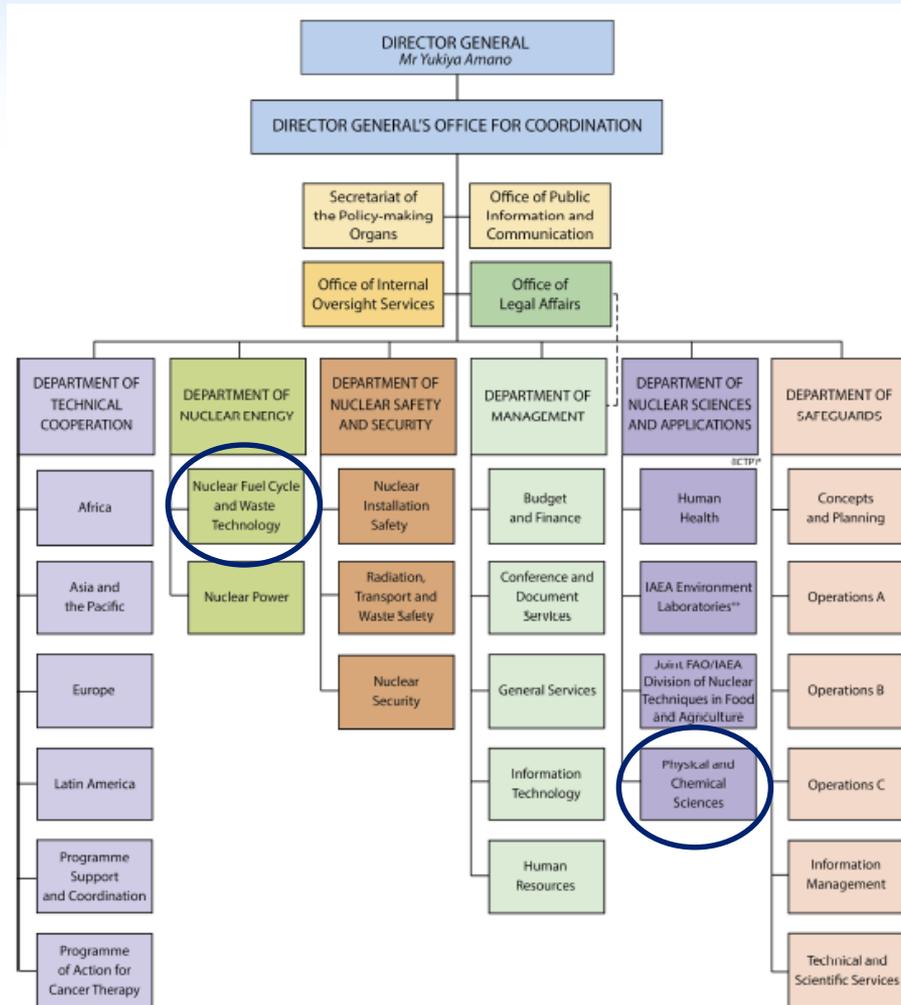
The Agency shall **seek to accelerate and enlarge** the contribution of atomic energy to **peace, health and prosperity** throughout the world.

Mission

To assist its Member States, in the context of social and economic goals, in **planning for and using nuclear science and technology for various peaceful purposes**, including the generation of electricity, and facilitate the transfer of such technology and knowledge in a sustainable manner to developing Member States.



IAEA Organization for Mo-99 Activities



Mechanisms for assistance

- **Coordinated Research Projects (CRPs)**– professionals/experts from 15-20 member countries (MS) participate in a research project of common interest, share the knowledge and experience and often achieve tangible results/success.
- **Training events** – need based; budget dependent thematic training events in specific topics- 15-20 MS professionals trained with focus on important aspects.
- **Thematic technical meetings:** professionals (typically 30-40) with expertise in the ‘theme’ from the MSs present their work; discussions often lead to further actions
- **Publications**
- **Conferences**
- **Technical Cooperation Projects**

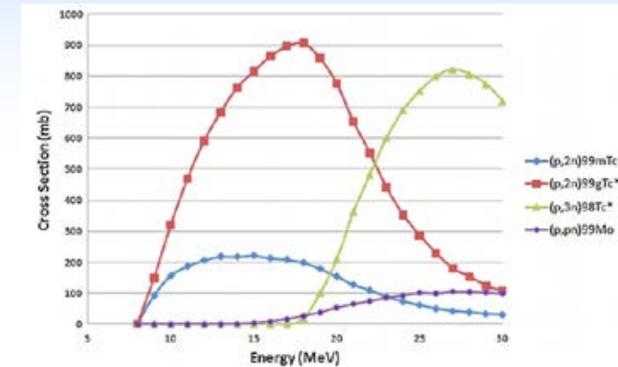


IAEA's Mo-99/Tc-99m related activities

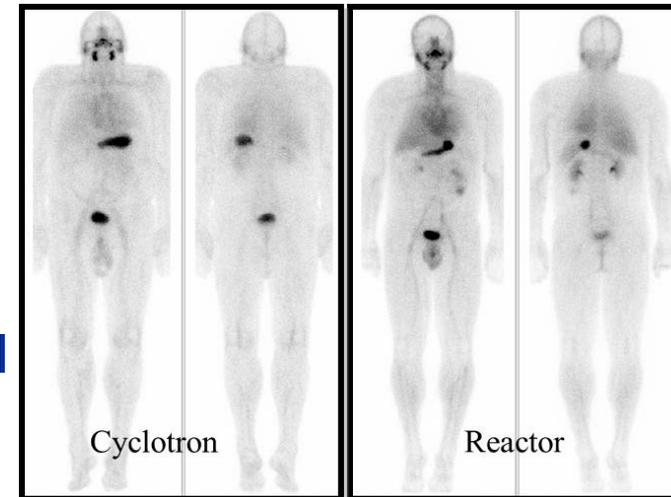
- Stability of supply of Mo-99 in Member States
- HEU minimization
- Indigenous production using non-HEU targets
- Small-scale production of Mo-99 or Tc-99m for local use and associated regulatory aspects
- New alternatives to Tc-99m radiopharmaceuticals
- Coordination and participation in the OECD-NEA's HLG-MR

Accelerator-based Alternatives to Non-HEU production of Mo-99/Tc-99m

- 2011-2015
- 18 participants from 16 Member States
- Production of Tc-99m in cyclotron - very successful
- Technology to produce several (>30) Ci Tc-99m per run in medical cyclotrons of energies below 24 MeV proven; clinical trials under way; regulatory approvals sought
- Monograph approved in Europe
- Self-sufficiency in hospitals/towns/country
- Good option for hospital or radiopharmacy; local productions
- Target specifications; reuse of targets etc. need consideration



Irradiation Parameters



Comparison of cyclotron- and reactor-based Tc-99m pertechnetate for the Univ. of Alberta Clinical Trial (cancer thyroid patients imaged post-thyroidectomy)

Sharing and Developing Protocols to Further Minimize Radioactive Gaseous Releases to the Environment in the Manufacture of Medical Radioisotopes, as GMP

- 2014 - **ongoing**
- Initiated as result of a request from a five Member States - May 2014
- First Research & Coordination Meeting - August 2015
- Second Research & Coordination Meeting – 06-10 March 2017
- Participants and observers from Australia, Belgium, Canada, France, Germany, Indonesia, The Netherlands, Pakistan, Poland, Rep. of Korea, USA.



Interregional Training Courses & Workshops

- **India** (Board of Radiation and Isotope Technology)
 - 22-27 June 2015
 - 15 participants from 12 MS
 - Lectures, demonstrations and visits:
 - Production and supply of Mo-99
 - Aspects related to (n,gamma) production
 - Generators with low specific Mo-99 (gel generator)
 - Solvent extraction of Tc-99m
 - Hot cells
 - Regulatory issues
- **Kazakhstan** (Institute of Nuclear Physics)
 - Planned for **2017-2018**, in tandem with the closing of the round robin activity
- **Round Robin Workshop**
 - To explore the use of Tc-99m radioactivity concentration units and high capacity absorbers for Mo
 - Planned for **2017-2018**

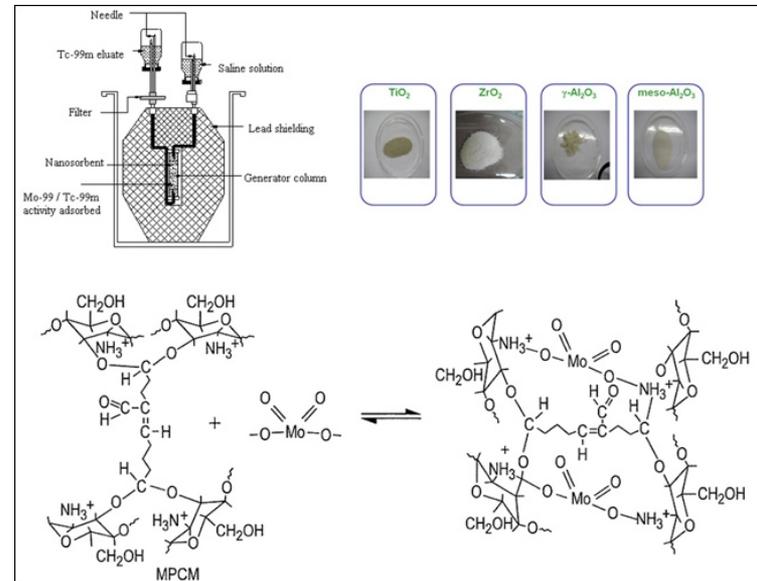
TM on New Ways of Producing Tc-99m and Tc-99m Generators

- 14-18 March 2016
- 17 participants from 8 Member States
- Objectives:
 - Evaluate alternative routes for the production of Tc-99m and Mo-99: (γ, n) reaction
 - Evaluate optimization of available generators
 - Evaluate current status and potential development of Mo-99/Tc-99m generators using low specific activity Mo-99
- Recommendations:
 - Round-robin: use of Ultralute concentration device Ultralute from Cyclopharm and new adsorber from Perma Fix
 - Training course and workshop
 - New CRP: 2017
 - Publication
- Concerns
 - Regulatory issues
 - Supply of enriched Mo target materials



New CRP: New Ways of Producing Tc-99m and Tc-99m Generators

- First Meeting: 13-17 November 2017
- 14 approved proposals
- Recommendation from Technical Meeting on same topic (March 2016)
- Aimed as use of low specific activity Mo-99 for generator preparation and accelerator production of Tc-99m (Mo-100 (γ,n) reaction)



- <https://www.iaea.org/newscenter/news/new-crp-new-ways-of-producing-tc-99m-and-tc-99m-generators>

Regulatory Aspects of Radiopharmaceutical Production

- 7-11 December 2015
- 9 participants from 8 Member States
- Objectives and recommendations:
 - ❑ To share experience of current radiopharmaceutical regulation status in participating MSs;
 - ❑ To define a work plan for IAEA to support MSs that require assistance in this issue, in the form of education, training and harmonization tools;
 - ❑ To evaluate the need for an IAEA publication with recommendations of how new facilities or those that need renovation can comply with national regulations.
- Workshop: 09-13 October 2017



Technical Cooperation Projects

- **Regional Project for Latin America region RLA6/0/76**
 - *Mejora de las Capacidades de Producción de Mo-99 (n,gamma) y otros radisótopos médicos seleccionados en Reactores de Investigación e Instalaciones de Procesamiento de la Región*
 - Chile, Mexico and Peru
 - 2016-2019
- **National Project in Peru**
 - Planned for **2018-2019**, to produce gel generators based on the technology of Kazakhstan

Symposium on Opportunities and Approaches for Supplying Molybdenum-99 and Associated Medical Isotopes to Global Markets

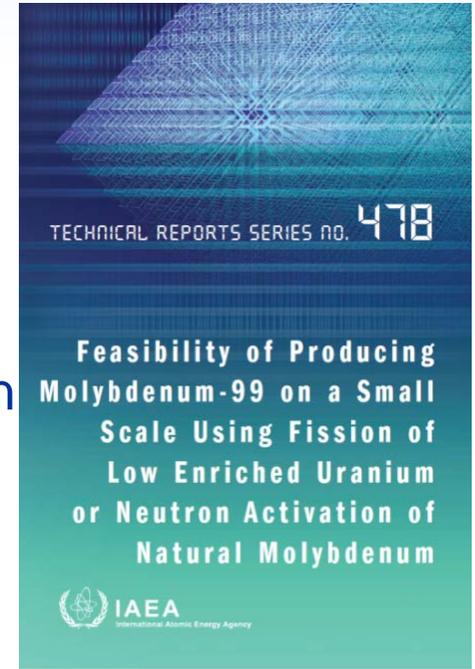
- 17-19 July 2017; IAEA HQ; 100 participants
- Co-hosted by the US National Academies of Sciences, Engineering, and Medicine and the Russian Academy of Sciences and held in cooperation with the International Atomic Energy Agency. Sponsored by the U.S. Department of Energy's National Nuclear Security Administration.
- Trends in global demand and supply for Mo-99 and associated medical isotopes.
- Prospects and approaches for developing new global supplies of Mo-99 and associated medical isotopes.
- Technical, regulatory, economic, and policy considerations for producing Mo-99 and associated medical isotopes for global markets using uranium-fission and other processes.



Research Reactor

Developing Techniques for Small Scale Indigenous Molybdenum-99 Production Using LEU Fission or Neutron Activation (n, γ)

- 2005-2011
- 14 Member States
- IAEA Technical Report Series No. 478: “Feasibility of Producing Molybdenum-99 on a Small Scale Using Fission of Low Enriched Uranium or Neutron Activation of Natural Molybdenum”
 - <http://www-pub.iaea.org/MTCD/Publications/PDF/trs478web-32777845.pdf>



Mo-99 production by (n, γ) – Round Robin

Objectives:

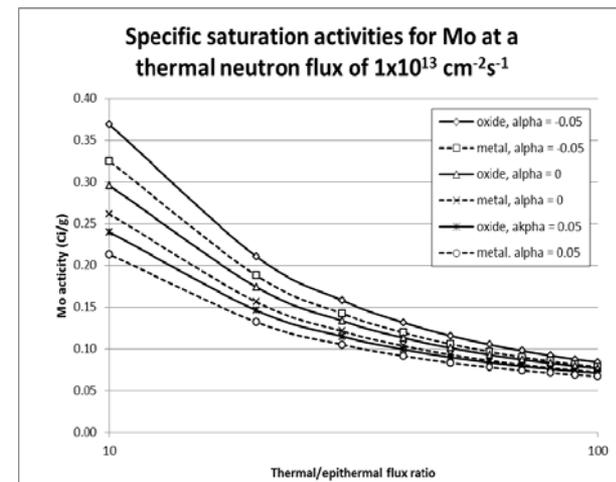
- Assist in organization of Round Robin for Mo-99 production by $^{0}n_1$ capture
- Promote non-HEU production pathways
- Facilitate estimates for local supply of Mo-99

Means:

- Provision of samples and procedures
- Advice and evaluation by international experts
- Irradiation results analysis, both individual & group
- Follow up workshops
- Expert missions to identified labs

Results:

- 16 Research Reactor facilities
- Analysis during December 2016 workshop
- Demonstrated ~1-3 Ci/g specific saturation activities with flux of $1 \times 10^{14} \text{ cm}^{-2} \text{ s}^{-1}$
- Paper summarizing results was published in the Journal of Radioanalytical and Nuclear Chemistry



Supporting the Global Deployment of Mo-99 Production Capacity for Nuclear Medicine Applications without the Use of HEU

- Started 2013
- Aimed at assisting small-scale, national-level producers in setting up their production capability
 - Not aimed at creating commercial producers
- Supports LEU fission or n,γ -based production
- Expert missions to Mexico, Morocco, Peru, Poland and Romania (Egypt and Malaysia conducted earlier)

Global Capabilities for the Production and Manufacture of Molybdenum-99 Targets

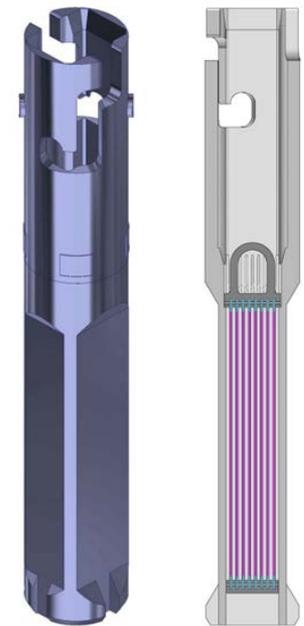
- 22-23 May 2017
- 22 participants from 15 Member States + EU Commission
- Objectives:
 - Discuss current and upcoming techniques and capabilities for the manufacture of targets used in the production of Mo-99



LEU foil target (USA)

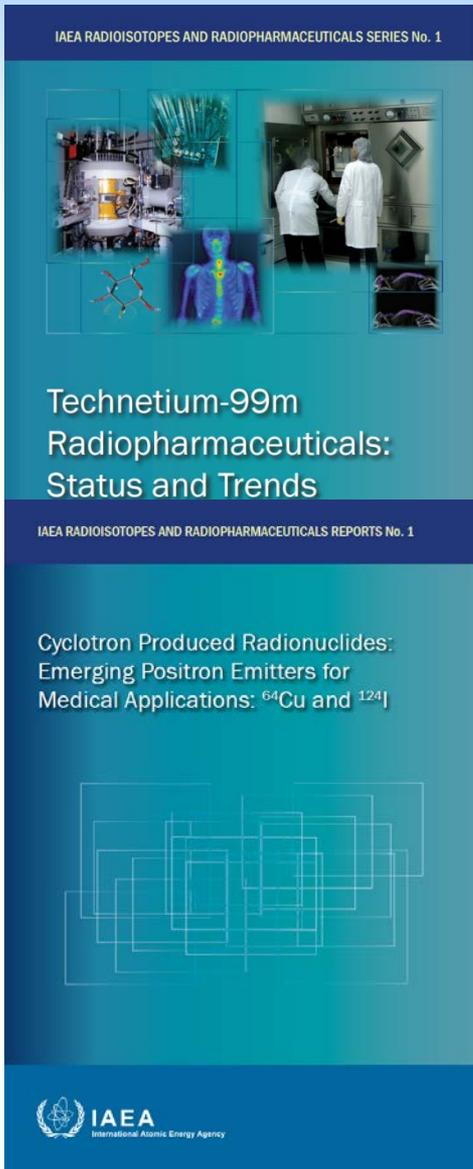


Irradiation baskets (Belgium)



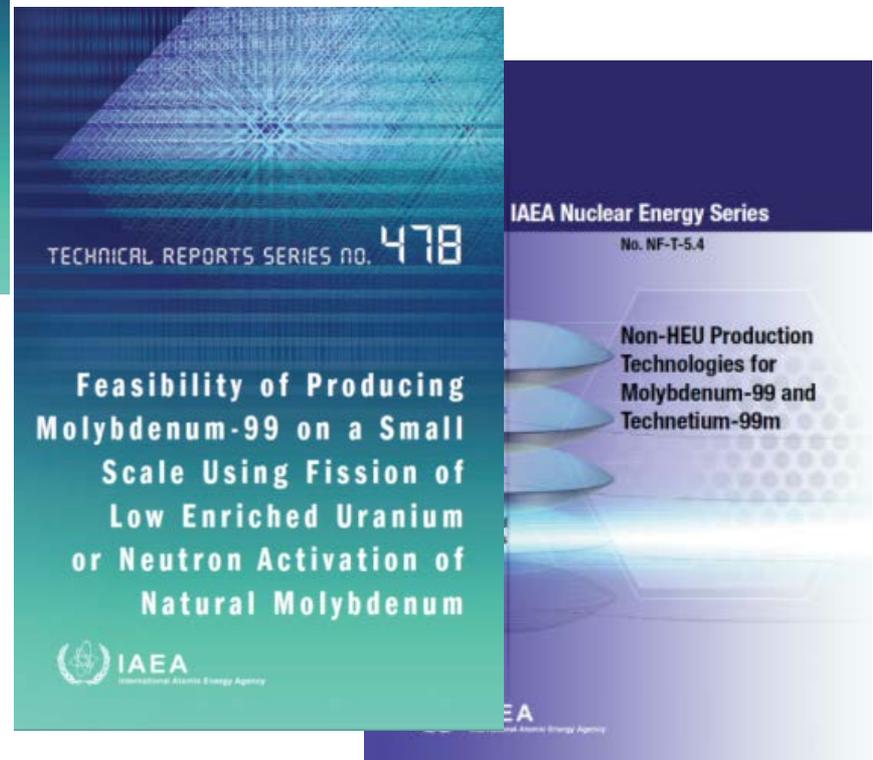
Target holder and plates (Korea)

Publications on Mo-99/Tc-99m



❑ Publication in progress

- ✓ *Reference Plan for Self Sufficiency in the Supply of Selected Radioisotopes Produced in Research Reactors: Latin America Case Study*



Upcoming Activities

CRPs

- 13-17 November 2017 – New Ways of Producing Tc-99m and Tc-99m Generators

Training Events

- TBD – Interregional Training Course in Kazakhstan
- TBD – Round robin on absorbers
- 2017 - 2nd AFRA Research Reactor School: Production of Radioisotopes in Rabat, Morocco

} Complementary events

Thematic Technical Meetings

- 09-13 October 2017 – Workshop on Regulatory Aspects of Radiopharmaceutical Production
- 2018 – 3rd Mo-99 target meeting

Conference

- 2019 – International Symposium on Trends in Radiopharmaceuticals (October)

Thank You!

