



IAEA

60 Years

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
11-15 September 2016 St Louis, MO

International Atomic Energy Agency (IAEA)



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

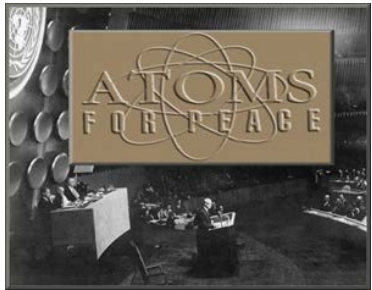


Statutory Mandate

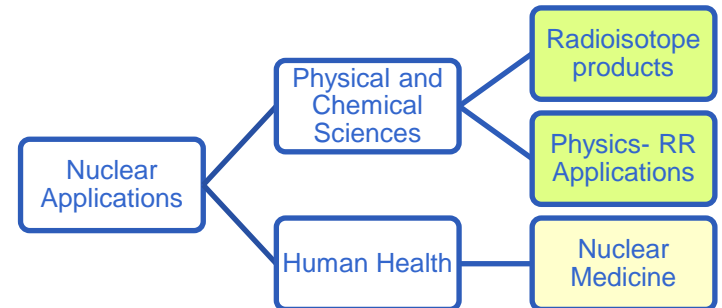
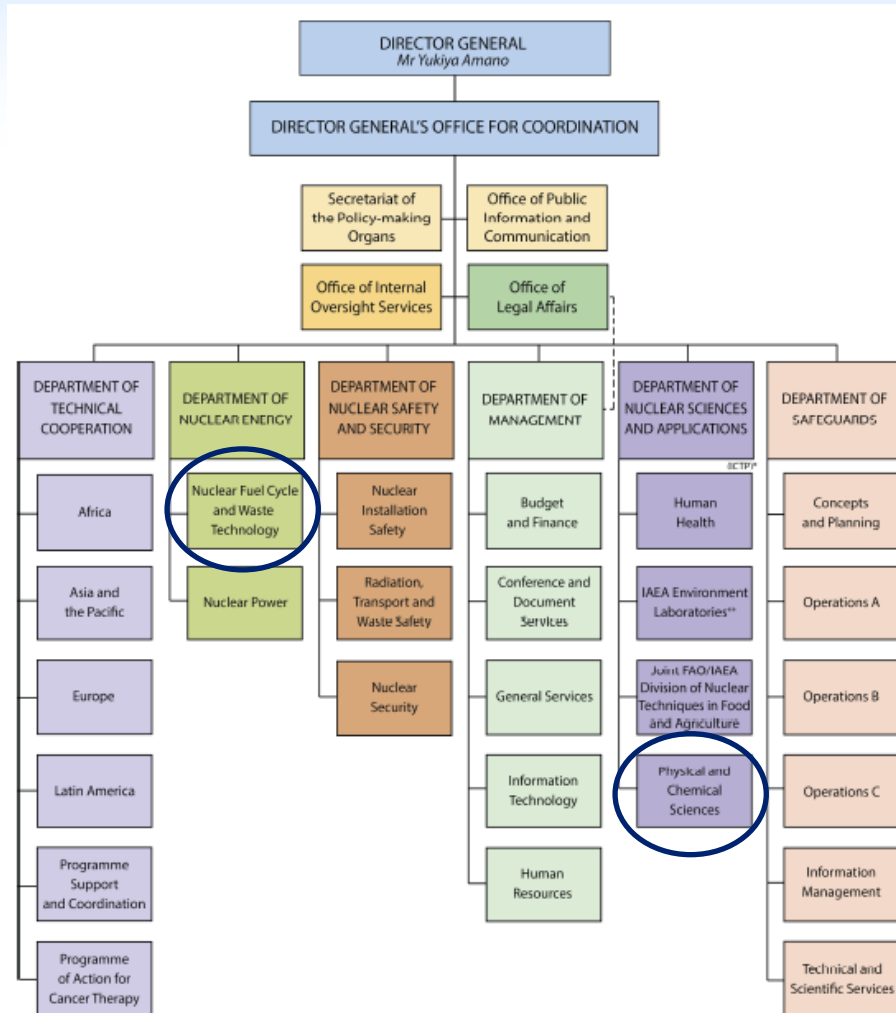
The Agency shall **seek to accelerate and enlarge** the contribution of atomic energy to **peace, health and prosperity** throughout the world.

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



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

Mechanisms for assistance

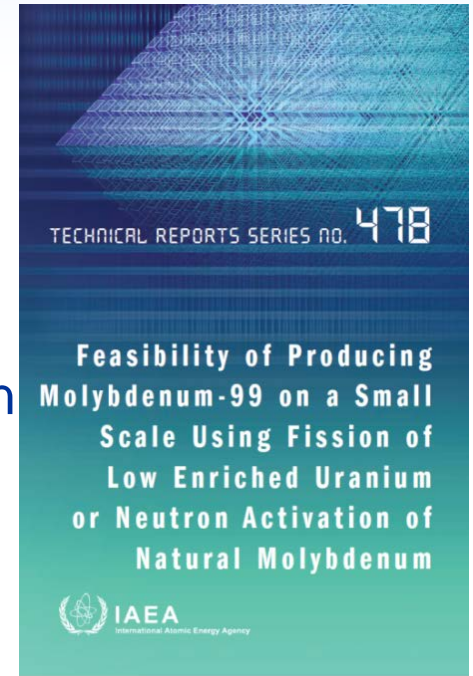
- **Coordinated Research Projects (CRPs)**– professionals/ experts from 15-20 member countries (MS) participate in a research project of common interest, share the knowledge and experience and often achieve tangible results/success.
- **Training events** – need based; budget dependent thematic training 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**



Coordinated Research Projects

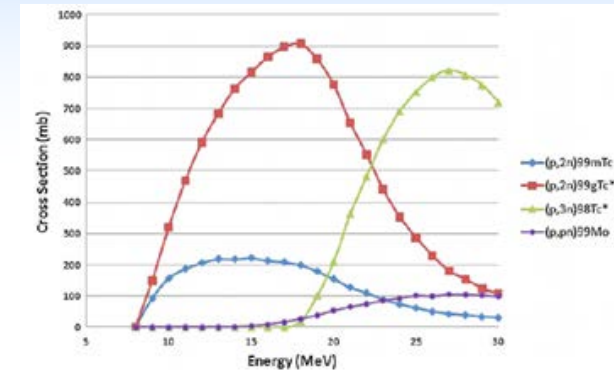
Developing Techniques for Small Scale Indigenous Molybdenum-99 Production Using LEU Fission or Neutron Activation (n, γ)

- 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>

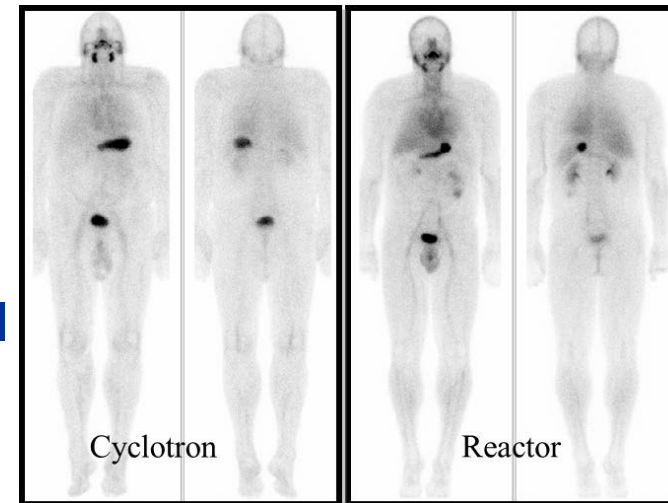


Accelerator-based Alternatives to Non-HEU production of Mo-99/Tc-99m

- 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
- 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 – planned 1Q 2017
- Participants and observers from Australia, Belgium, Canada, France, Germany, Indonesia, The Netherlands, Pakistan, Poland, Rep. of Korea, USA.



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

- Planned new CRP for 2017
- 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



Training Events

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

Objectives:

- Assist in organization of Round Robin for Mo-99 production by $^{0}\text{n}_1$ capture
- Promote non-HEU production pathways
- Facilitate estimates for local supply of Mo-99

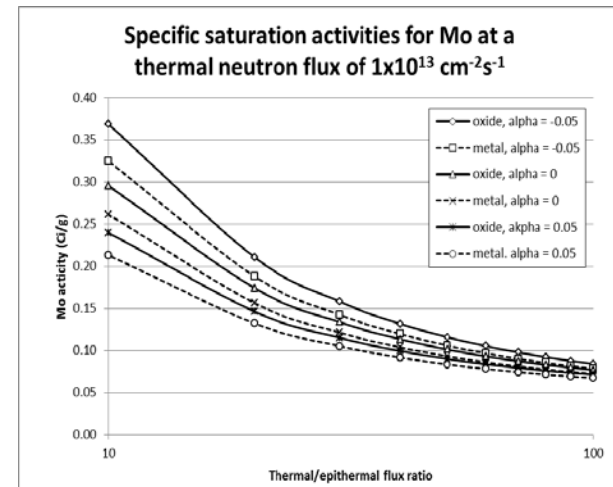
Means:

- 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 RR facilities
- Analysis - December 2015 workshop
- Demonstrated that ~1-3Ci/g specific saturation activities with flux of $1 \times 10^{14} \text{ cm}^{-2}\text{s}^{-1}$
- Summary paper accepted for publication 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)

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, 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

Thematic Technical Meetings

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

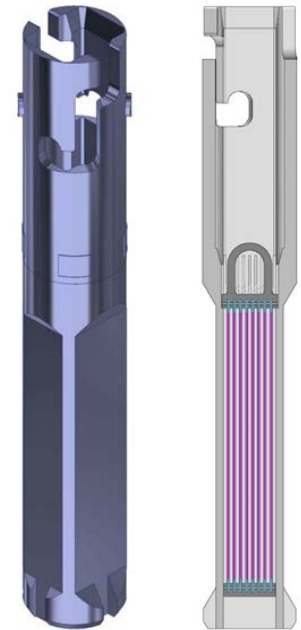
- 20-21 October 2015
- 31 participants from 15 Member States + EU Commission
- Objectives:
 - Discuss current and upcoming techniques and capabilities for the manufacture of targets used in the production of Mo-99



LEU foil target (USA)



Irradiation baskets (Belgium)



Target holder and plates (Korea)

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.



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

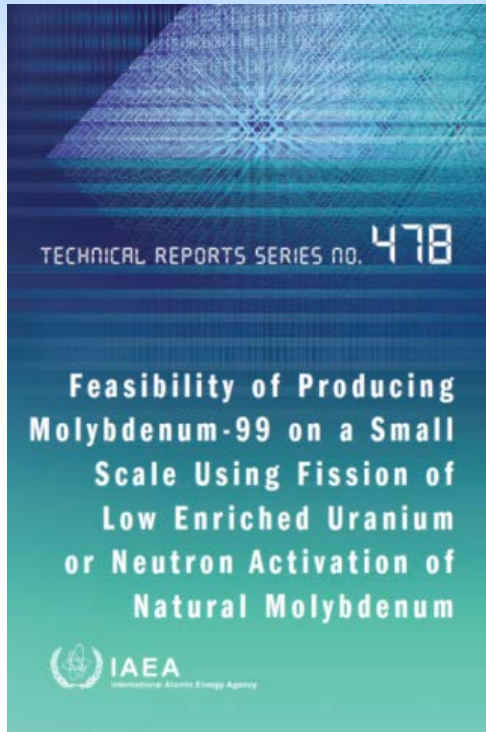
- 14-18 March 2016
- 17 participants from 8 Member States
- Objectives:
 - Evaluate alternative routes for the production of Tc-99m and Mo-99
 - Evaluate optimization of available generators
 - Evaluate current status and potential development of Mo-99/Tc-99m generators using low specific activity Mo-99
- Recommendations:
 - Round-robin
 - Training course
 - New CRP
 - Publication
- Concerns
 - Supply of enriched Mo target materials
 - Regulatory issues



*TCM-AUTOSOLEX Separation module with Control Unit
(India)*

IAEA Publications

Publications on Mo-99/Tc-99m



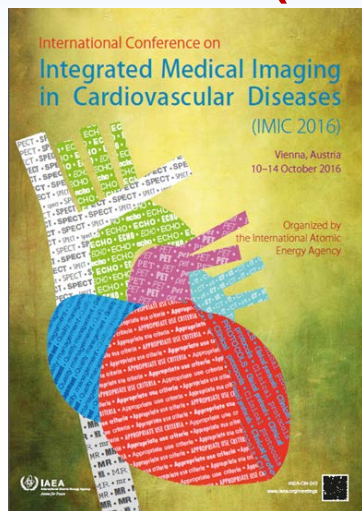
❑ Publication in progress

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

Conferences & Upcoming Activities

Upcoming IAEA Conferences

IMIC 2016 (Oct 10-14, 2016)



- Special Plenary Session on 12 Oct.
- Session VI : Radiopharmacy
 - *Kevin Charlton – OECD role (HLG-MR)*
 - *Sally Schwarz – GMP in US (FDA; IND)*
 - *Adriano Duatti – Cardiac agents (Tc-99m, Tl-201 & PET)*

2019 – International Symposium on Trends in Radiopharmaceuticals
(approved) proposed date 06-10 May 2019

Upcoming Activities

CRPs

- 27 Feb. – 3 March 2017 (*proposed*): RCM #2 of Emissions CRP
- TBD – New Ways of Producing Tc-99m and Tc-99m Generators

Training Events

- 2017 – Interregional Training Course in Kazakhstan
 - 2017 – Round robin on absorbers
- } Complementary events

Thematic Technical Meetings

- 2017 – 2nd Mo-99 target meeting
- 2017 – Workshop on Regulatory Aspects of Radiopharmaceutical Production

Thank You!

