



"IAEA Radioisotope Program"

TRIUMF SCIENCE WEEK - 2020

18-08-2020

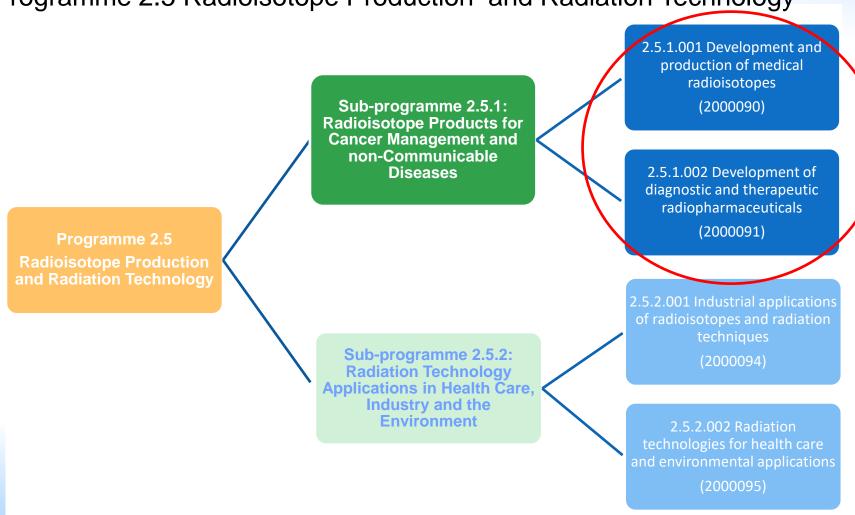
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Programme description/objectives



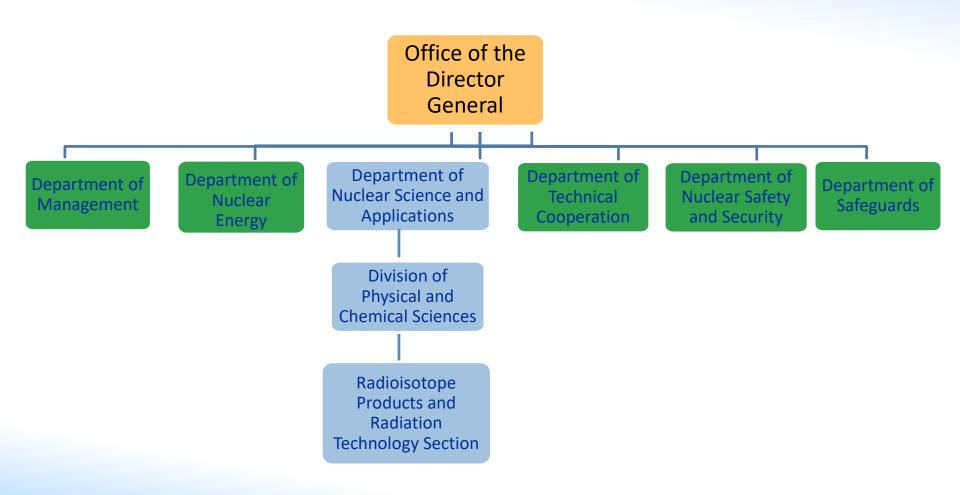
Radioisotope Products and Radiation Technology Section

Programme 2.5 Radioisotope Production and Radiation Technology





IAEA Organization – RPRT Section





NAPC Radioisotope Products and Radiation Technology Section



Medical and industrial radioisotopes

CH preservation



Material modification

Radiation in radiopharmacy, industry, arts, sciences, and much more

Radiopharmaceuticals





Sterilization of Industrial and Healthcare products

NDT, Nucleonic gauges, radiotracers

IAEA Projects: RPRT Section





Coordinated Research Projects (CRP-R&D) 15



Technical Cooperation Projects (TC-implementation) 160





Regular program activities

Support to
Conferences

Meetings
(CM, TM) /
Conferences

Participation in complimentary international activities

Collaborating Centres (CC) 10

General
Conference
side-events
and Scientific
Forum

Missions

Publications

Planning of activities



- Planning & Budget: biannual cycles (18-19; 20-21; 22-23)
- Annual meeting planning
- Inputs:
 - GC resolutions (Mo-99)
 - TOs experience and network
 - Requests from MSs (health regulatory issues)
 - Experts recommendations (meetings, missions, etc)
 - Evaluation of IAEA Conferences
 - Recommendations/Collaborations: key partners (EC-JRC, WHO)
 - SAGNA recommendations
 - Collaborating Centres
 - EB funding
 - Alignment with SDGs

Resolutions GC63 (2019)



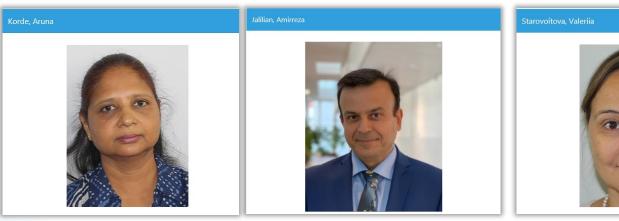
- A. Non power nuclear applications 1. General
- Calls upon the Secretariat to continue to address identified priority needs and requirements of Member States in the areas of nuclear science, technology and applications, such as:
 - □ i. use of radioisotopes and radiation in human health, including through enhancing access and quality,
 - □ x. use of cyclotrons, research reactors and accelerators for the production of affordable radiopharmaceuticals
- * 18. Requests the Secretariat to continue to provide to interested Member States, upon request, technical assistance regarding production and transport of medical isotopes and radiopharmaceuticals;
- * 19. Requests the Secretariat to continue providing assistance to Member States with capacity building for the development, production and quality control of new generations of therapeutic radiopharmaceuticals (such as alpha emitters);

Resolutions GC63 (2019)

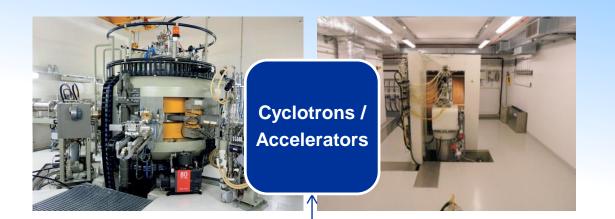
- Urges the Secretariat to continue to implement activities that will contribute to securing and supplementing the molybdenum-99/technetium-99m production capacity, including in developing countries, in an effort to ensure the security of supplies of molybdenum-99 to users worldwide and further urges the Secretariat to continue its cooperative work towards this goal with related initiatives undertaken by other international organizations such as the OECD Nuclear Energy Agency;
- 22. Requests the Secretariat, upon request from interested Member States, when technically and economically feasible, to provide technical assistance to emerging national and regional efforts to establish non-HEU based molybdenum-99 production capabilities, and to provide technical assistance to transition existing production capabilities to utilize non-HEU-based methods and facilitate training activities such as workshops to support Member States in their efforts to achieve self-sufficiency in local production of medical radioisotopes and radiopharmaceuticals;
- Urges the Secretariat to continue exploring the use of accelerators for various radiation technology applications and to facilitate demonstrations and training for interested Member States;
- 24. Requests the Secretariat to make efforts together with Member States in developing industrial irradiation facilities such as electron accelerators and their accessories for use in, inter alia, healthcare practices, crop improvement, food preservation, industrial applications, sanitization and sterilization, and further requests the provision of technical support for the use of research reactors in the production of radiopharmaceuticals and industrial radioisotopes;



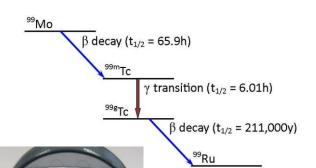
Activities/Applications







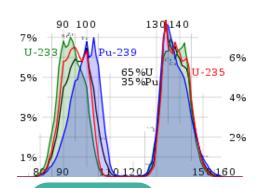




Radionuclide generator

Production of radioisotopes

Mo-99 and Ac-225

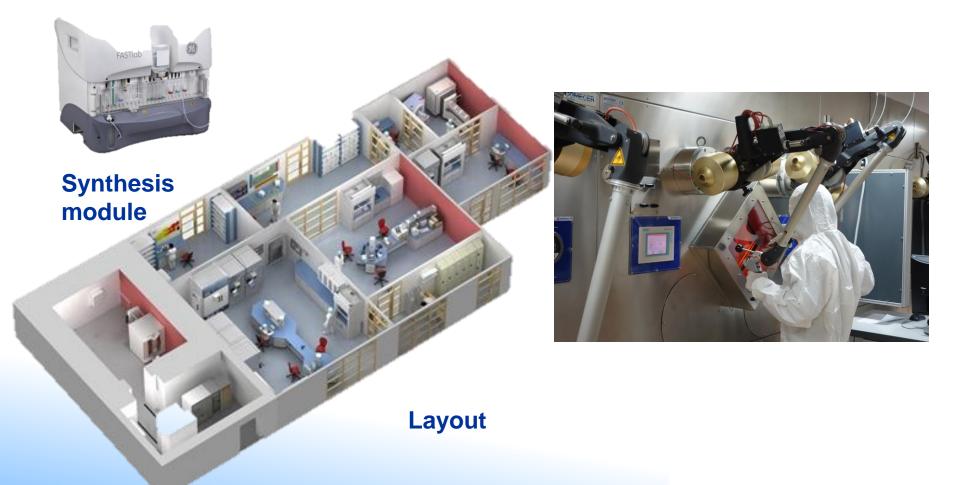


Research Reactor





Production of Radiopharmaceuticals



Main activities



1. Production of radioisotopes

2. Production of radiopharmaceuticals



3. Quality control and assurance

4. Conferences, meetings, capacity building



5. Education (e-learning, training modules, sylabus for Universities)

6. Regulatory issues: Due to the increasing complexity of radiopharmaceutical preparations and the mandatory requirement of patient's safety, there exists a widespread demand to support regulators and preparation of guidelines of Good Manufacturing

Practice (GMP)

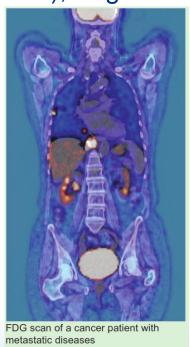
7. Publications: CRPs, guidelines



8. International Pharmacopeia in cooperation with WHO

Radioisotopes and Radiopharmaceuticals for Diagnosis and Therapy

- Radiopharmaceuticals for SPECT (Single Photon Emission Computed Tomography): Tc-99m, In-111, Ga-67...
- Radiopharmaceuticals for PET (Positron Emission Tomography): F-18, Ga-68, Cu-64, Zr-89....
- Radiopharmaceuticals for therapy: Lu-177, Y-90, I-131, Cu-67, Cu-64, alpha emitters(Ac-225), Auger





PET/CT

SPECT/CT bone

Radioisotope production technologies



CRPs

- Production and utilization of Emerging Positron Emitters for Medical Applications with an Emphasis on Cu-64 and I-124 (2010-2014)
- Accelerator-based Alternatives to Non-HEU production of Mo-99/Tc-99m (2011-2015)
- Sharing and Developing Protocols to Further Minimize Radioactive Gaseous Releases to the Environment in the Manufacture of Medical Radioisotopes, as Good Manufacturing Practice (August 2015)
- Therapeutic Radiopharmaceuticals Labelled with New Emerging Radionuclides (⁶⁷Cu, ¹⁸⁶Re, ⁴⁷Sc) – (2016-2019)
- New Ways of Producing Tc-99m and Tc-99m Generators 3rd RCM in 2021
- Production of Cyclotron-Based Gallium-68 Radioisotope and Related Radiopharmaceuticals – 1st RCM in 2021

Radiopharmaceuticals: production, quality aspects and clinical use



CRPs

- Development of Ga-68 based PET-Radiopharmaceuticals for Management of Cancer and other Chronic Diseases (2010-2015)
- ❖ Development and preclinical evaluations of therapeutic radiopharmaceuticals based on Lu-177 and Y-90 labeled monoclonal antibodies and peptides (2011-2015)
- Nanotheranostic: Nanosized delivery systems for radiopharmaceuticals (2014-2019)
- Cu-64 Radiopharmaceuticals for Theranostic Applications (2016-2020)
- Production of Zr-89 and Development of Zr-89 Radiopharmaceuticals – new 2019 – 1st RCM 2021



TMs/CMs 2020



- Regional training workshop on Preparation and Quality Control of Alpha/Beta Emitter Labelled Peptides (Latin America-Colombia): 2021
- Regional Training course on Preparation and Quality Control of SPECT Radiopharmaceuticals (Africa): 2021
- TM on New Generation of Technetium-99m Kits for Oncology Applications: 2021
- CM on IAEA Publication on Nanosized Delivery Systems of Radiopharmaceuticals
- CM on Recent Advances in the Production and Quality Control of Fluorine-18 radiopharmaceuticals
- CM on the Formulation of WHO/IAEA Guidance Documents on Good Manufacturing Practices for Radiopharmaceutical Products

TMs/CMs 2021 (not approved yet)

- IAFA
- CM on the Development of Molecular Probes for Multimodality Imaging
- CM on Preparation of Guidelines for Design and Operation of SPECT Radiopharmacy Facility
- CM on the Status of Alpha Emitters and Radiopharmaceuticals
- TM on the Preclinical Testing of Radiopharmaceuticals
- CM on the Status of Emerging Radioisotopes of Arsenic and Antimony for Radiopharmaceutical Development
- TM on Practical Aspects Related to the Production of Molybdenum-99 by Photonuclear Reaction: CII
- CS on the Preparation of Technical Document on Development of Radiotracers for CNS: bench to bedside
- Technical Workshop on Production of Theranostic Radiometals using a Medical Cyclotron
- TM on the Status of Lu-177 Theranostic Radiopharmaceuticals
- CM on Preparation of Guidelines for Design and Operation of PET Radiopharmacy Facility

Cycle 22/23 (planning stage)



- New CRPs: Ac-225; new kits for Tc-99m; new kits for Theranostic
- Auger emitters
- Radioisotopes/Radiopharmaceuticals in COVID-19
- Women in Radiopharmaceutical Sciences
- WHO

Recent Publications: more 10...



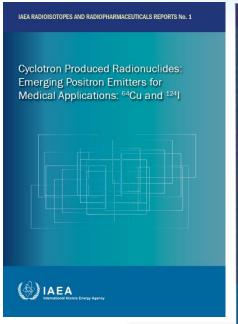


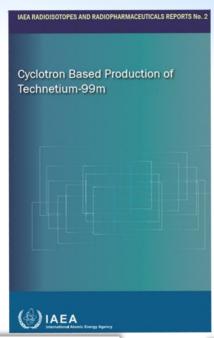
IAEA TECDOC SERIES

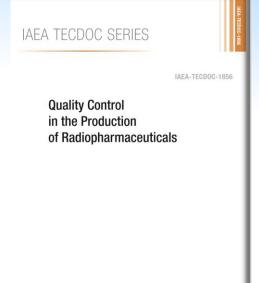
MAEA-TECDOC-1883

Gallium-68 Cyclotron
Production





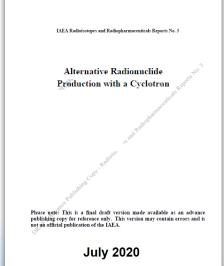




Production, Quality Control and Clinical Applications of Radiosynovectomy agents

Please note: This is a final draft version made available as an advance publishing copy for reference only. This version may contain errors and is not an official publication of the IAEA.

July 2019



Copper-64
Radiopharmaceuticals;
Production, Quality Control
and Clinical Applications

(A) IAEA

IAEA Technical Report Series

December 2019

IAEA

TC Projects

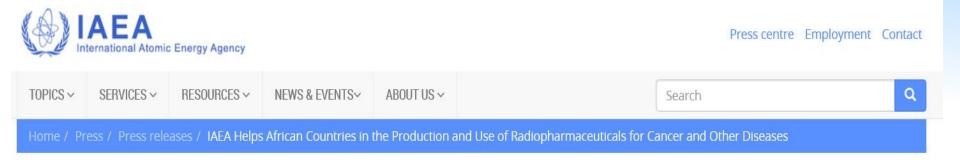
- **❖ More than 160 projects**
- * Capacity Building : FE, SV, NTC, Experts
- Setting up facilities through TC projects
 - ✓ Technetium-99m Generator Production facility;
 - ✓ Cyclotron facility for PET radiopharmaceuticals and RPHs;
 - ✓ Upgrade of gamma facilities
 - ✓ Training/certification on NDT and radiotracers for industry





Initiation of a 5 year project in Africa





IAEA Helps African Countries in the Production and Use of Radiopharmaceuticals for Cancer and Other Diseases

21/2018

Kampala, Uganda

MAY 1 2018



Related resources

- % Radiopharmaceutical production
- Radiopharmaceuticals A Key Component of Nuclear Medicine

Successful training course on alpha and beta emitter peptides, Poland June 2018





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New Technique to Fight Prostate Cancer: IAEA organizes first-of-a-kind training for Radiopharmacists

Aleksandra Peeva, IAEA Department of Nuclear Sciences and Applications

JUL 10 2018



For the first time, radiopharmacists from across Central and Eastern Europe learned about an emerging technique in treating prostate cancer at an IAEA course organized at the National Centre for Nuclear Research in Poland last

Related Stories



African Radiopharmacists Put New Skills to Use



IAEA Helps African Countries in the Production and Use of Radiopharmaceuticals for Cancer and Other Diseases

Related Resources

- Radiopharmaceuticals A Key Component of Nuclear Medicine
- % Diagnostic radiopharmaceuticals
- % Radionuclide therapy
- Ministerial Conference on Nuclear Science and Technology: Addressing Current and Emerging Development Challenges, 28-30 November 2018



Collaborations

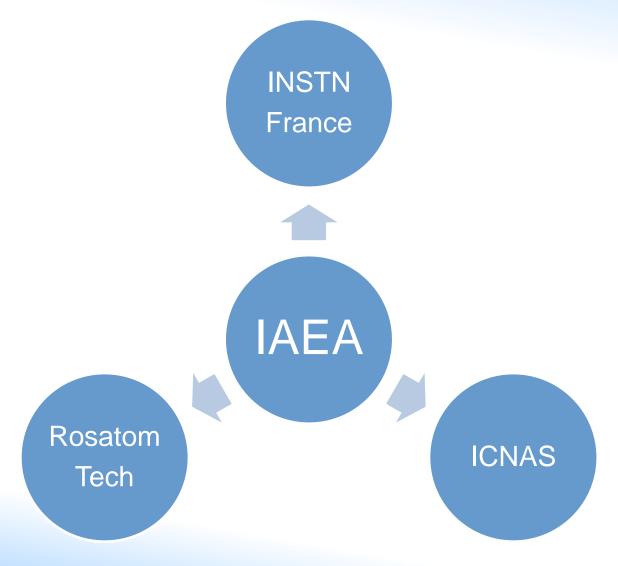
External Collaboration



- CCs
- EC-JRC
- SRS, EANM, iiA, ISTRA,
- DOE labs
- ■TRIUMF, CNL, CII, Universities
- CERN
- US National Academies of Sciences, Engineering, and Medicine, Russian Academy of Sciences
- KOICA-KAERI-WCI (3 courses/year)
- WHO
- PA:EC, Okayama University (BNCT), WNU



Collaborating Centres - Radiopharmacy

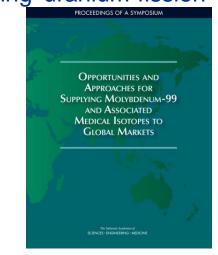


Symposium on Opportunities and Approaches for Supplying Molybdenum-99 and Associated Medical Isotopes to Global Markets

- 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

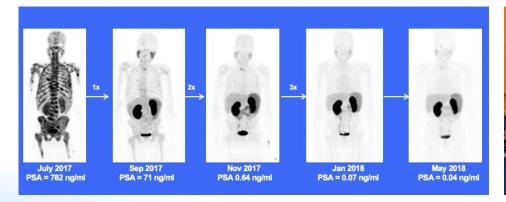
other processes.



Workshop on Supply of Ac-225

- 09-10 October 2018; IAEA HQ; 80 participants, 17 MSs
- In collaboration with EC-JRC (PA: NA and EC)
- Cross cutting: NDS, PS, NEFW, NMDI, NS
- Trends in global demand and supply for Ac-225
- Motivation: excellent clinical trials results of Ac-225-PSMA
- Report finalized
- New TM in December 2019: guidelines
- New CRP with NAHU







Mike Sathekge et al, European Journal of Nuclear Medicine and Molecular Imaging (2019) 46:129–138

Collaboration IAEA-WHO





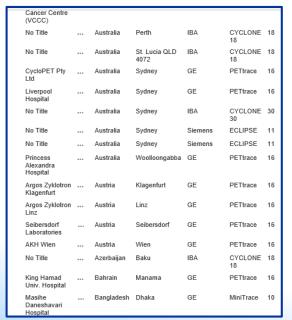
- PA being prepared
- Update of monographs for radiopharmaceuticals
- Review of general monograph for radiopharmaceuticals: meeting May 2019
- Guidelines on GMP for radiopharmaceutical production:
 - Good Radiopharmaceutical Practises: update guidelines on Annex 3 (2003): Meeting at IAEA in 05-09 November 2018 with experts
 - The guidelines were opened to public consultation in early 2019.
 - Meeting June 2019 to evaluate comments
 - Guidelines published

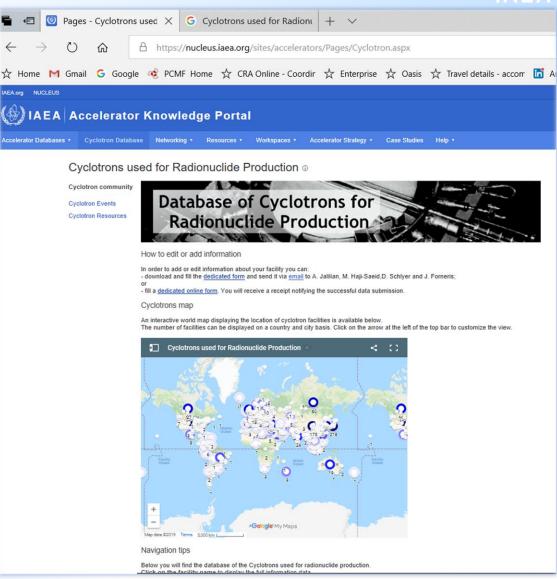


Databases

Database: Cyclotrons used for Radionuclide Production

- >1350 cyclotrons
- 89 MSs
- Online data inquiry
- World-wide map
- Continuous data acquisition
- Live and streaming
- List of products
- Contact info
- Still in completion process





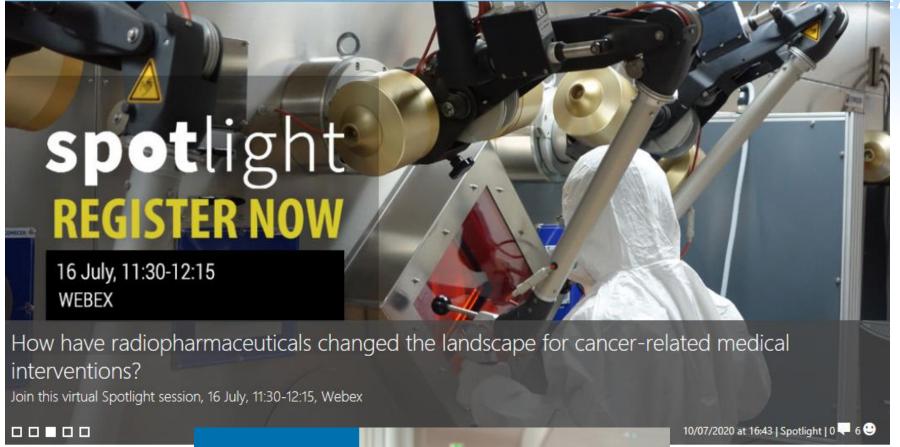
https://nucleus.iaea.org/sites/accelerators/Pages/Cyclotron.aspx



Spotlight, webinars, conferences

Spotlight on Radiopharmaceuticals





Your Weekly
InSite

Webinar









COVID-19 Pandemic: Supply of Medical Radioisotopes and Radiopharmaceuticals

The IAEA, in collaboration with International Organizations, is committed to supporting facilities for radioisotope and radiopharmaceutical production during current COVID-19 pandemic. Join us on the webinar "COVID-19 Pandemic: Supply of Medical Radioisotopes and Radiopharmaceuticals" on Thursday, April 23, 2020, 14.00 - 15.30 CET (Vienna time)

The webinar will have the format of a virtual town-hall meeting, in which an international panel of experts will answer questions related to how to deal with the production of medical radioisotopes and radiopharmaceuticals & its supply for clinical use during the COVID-19 pandemic.

The webinar will address practical considerations and challenges:

- 1. Operation of reactor- and accelerator-based production facilities
- 2. Distribution and supply of radioisotopes and radiopharmaceuticals
- 3. Radiopharmacy operation, including staffing
- 4. Extra safety considerations during the crisis

This webinar will also function as a platform to share and exchange experience and best practice. There will also be a question and answer session with experts.

Chair: MrJoao OssoJr (IAEA)

Date: Thursday, April 23, 2020

Time: 14:00 - 15:30 CET (Vienna time)

Modality: Webinar

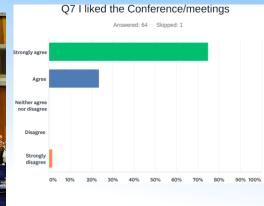
Platform: WebEx

- 821 attendees from 74 MSs
- 18 short presentations
- 4 from IAEA

ISTR-2019

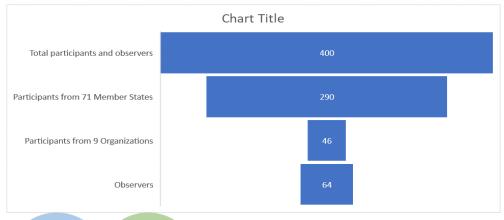






40%

Women





48% 52% Grants

Men

113
Total
Grants
Sates

33 000€ 36

60%

Men

Network of Women in Radiopharmaceutical Sciences





Future Conferences









Thanks!

